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PRINCIPAL INVESTIGATOR: Edwin G. Wilkins, M.D.

CONTRACTING ORGANIZATION: University of Michigan
Ann Arbor, Michigan 48109

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Edwin G. Wilkins, M.D.

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)University of Michigan
Ann Arbor, Michigan 48109

Email: ewilkins@umich.edu

**8. PERFORMING ORGANIZATION
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Initiated in September of 1994 and continuing through 1999, the Michigan Breast Reconstruction Outcome Study (MBROS) was designed to prospectively compare the long-term outcomes of implant, pedicle TRAM and free TRAM breast reconstructions. Analysis of psychosocial, functional and aesthetic data has been ongoing. Analysis of the psychosocial data of 250 patients suggests that patients in all three surgical groups experienced a significant increase postoperatively in general mental health, emotional well being, and functional well being. No significant differences between the groups were identified. Patients undergoing delayed tissue expander/implant reconstruction experienced a significantly greater increase in vitality, but a significantly smaller increase in satisfaction with the aesthetic results, than patients undergoing delayed TRAM procedures. No difference in the increase in vitality or aesthetic satisfaction was observed between surgical groups for patients undergoing immediate reconstruction. In a preliminary analysis of objective methodologies for assessment of aesthetic outcomes, we found that TRAM (pedicle and free) reconstruction offered superior dimensional symmetry than implant reconstruction. These symmetry differences were significantly better in many groups. Furthermore, pedicle TRAM seemed to offer greater symmetry than free TRAM in all measured groups.

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PI - Signature

Edwin G. Wilkins, M.D.

9/9/99
Date

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INTRODUCTION

The objective of the Michigan Breast Reconstruction Outcome Study (MBROS) is to compare the long-term outcomes of the most common techniques of post-mastectomy breast reconstruction: tissue expansion/breast implant procedures, transverse rectus abdominis musculocutaneous (TRAM) flaps (free and pedicle), and latissimus dorsi flap/implant techniques. A four year prospective study, the project is adapting existing instruments and formulating new methodologies to assess outcomes in five categories: complication rates, aesthetic results, functional results, psychosocial status and costs. Study results will provide much needed information to patients, providers, and payers for determining the procedure of choice. In addition, the research will establish standardized methods for evaluation of breast reconstruction results in future studies. Finally, initial data assembled by this research can also be used for long-term analysis of breast reconstruction outcomes.

BODY

A. Project Status

MBROS was funded by the U.S. Army in July of 1994, for a four year period. After hiring and training of project personnel, the study was initiated in late September, 1994. The study has received two time extensions and will continue until May, 2000. The additional time has allowed us to continue recruitment during years three and four of the study and to follow patients recruited during year three for the full two year study period. During the study, we have recruited 460 patients. Of these, 63 have been withdrawn from the study, leaving 397 participants. We discontinued enrollment in September, 1998, and will continue follow-up until May, 2000.

As detailed on page 17 of our original proposal, we stated that a total of 462 patients would be necessary for the study. We estimated that, given current case volumes among participating surgeons, 850 patients would be eligible for recruitment during the study period. We further estimated that we could recruit at least 60 percent of eligible individuals, resulting in 510 study patients. We fell somewhat short of the 510 patients, primarily due to sparse patient recruitment by several of the referring physicians.

In the reviewer's response to our 1998 Annual Report, clarification was requested for the number of patients we planned to recruit during the study. In the statement of work, page 24 of the original proposal, we stated we would recruit 425 patients in year one and 425 patients in year two for a total of 850 patients. As noted in the previous paragraph, 850 patients was the total number of breast reconstruction patients all participating physicians would see during the study period. We expected to recruit only 60 % of the total patients seen. Therefore the total number of patients recruited should have been 510, or 60% of the 850 total breast reconstruction patients. The recruitment rate would be 255 patients per year, not 425 as stated.

B. Status of Patient Enrollment

Patient follow-up continues and we are still collecting data. As table one indicates, we have pre-operative and one year post-operative questionnaire data on 329 patients. Of these, 225 also have completed the second post-operative questionnaire. We have pre- and post-operative physical assessments on 292 patients, with 186 of these patients also having completed their second post-operative physical assessment exam.

Table 1 - Status of All Patients Enrolled

Status	Number	Three Quest. Complete	Two Quest Complete	Three Phys Assessments Complete	Two physical Assessments Complete
Active Patients	127	13	77	14	69
Completed Patients	228	207	15	171	26
Limited Patients	42	5	12	1	12
Withdrawn Patients	63				
Total	460	225	104	186	107

C. Continue acquisition of clinical data from participating hospitals and surgeons.

Chart reviews have been completed on 207 patients who have come to the end of the two-year study period. This fall, chart reviews will be completed in New Orleans and in Toronto, Ontario Canada, where we have large numbers of enrollees.

D. Continue collection of cost data from participating hospitals.

The comparison of costs between the TRAM and implant methods of reconstruction is one of the five categories in which patient outcomes are being studied. The total cost of treatment for each study patient consists of all professional and hospital costs associated with the patient's hospitalization for the reconstruction, plus the costs of any subsequent care received (inpatient or outpatient) that is related to the reconstruction.

We have collected billing data from the participating hospitals in the United States on 258 primary procedures and 249 secondary procedures, and continue to collect these data as our patients complete their treatment. Negotiations are continuing with the Ontario health care system to collect financial data from the participating Canadian Centers. The data we have collected generally include a detailed list of services provided, the individual charges associated with each service, and total charges. After reviewing these data, we realized that it would be virtually impossible to assign UM RVUs to each line item on the bills. Therefore, we have decided to limit our RVU assignments to those items that are likely to account for the majority of patient costs and the majority of variability in patient costs: inpatient daily room costs, operating room time, recovery room time, and non-professional anesthesia time (i.e., CRNAs). These are services we can identify from each hospital's bills *and* assign UM RVUs. The following table illustrates this financial analysis.

MBROS Financial Analysis To-Date

Patients are 1-2 years post-surgery. All primary and secondary procedures included, excluding tattooing and nipple reconstruction, unless the nipple reconstruction was done in conjunction with another procedure.

Immediate Reconstruction Patients

Group	<i>n</i>	Average Resource Use			Charges ²
		OR Hours	Inpt Days	UM RVUs ¹	
Bilateral implant	13	9.3	4.9	3,505	23,299
Bilateral Free TRAM	7	14.8	7.0	4,598	30,090
Bilateral Pedicle TRAM	8	9.6	8.1	4,197	25,029
Unilateral implant	29	7.2	5.0	3,245	18,629
Unilateral Free TRAM	22	12.0	6.8	4,158	27,217
Unilat Pedicle TRAM	49	8.5	5.3	3,190	18,798

Group	<i>n</i>	Ratios of Resources Used ³			
		OR Hours	Inpt Days	UM RVUs	Charges
Bilateral implant	13	1.3	1.0	1.1	1.2
Bilateral Free TRAM	7	2.1	1.4	1.4	1.6
Bilateral Pedicle TRAM	8	1.3	1.6	1.3	1.3
Unilateral implant	29	1.0	1.0	1.0	1.0
Unilateral Free TRAM	22	1.7	1.4	1.3	1.5
Unilat Pedicle TRAM	49	1.2	1.1	1.0	1.0

Delayed Reconstruction Patients

Group	<i>n</i>	Average Resource Use			Charges ²
		OR Hours	Inpt Days	UM RVUs ¹	
Bilateral implant	1	11.5	7.0	5,178	32,300
Bilateral Free TRAM	1	15.0	8.0	4,925	26,445
Bilateral Pedicle TRAM	2	14.2	7.0	4,879	31,990
Unilateral implant	6	5.6	1.7	2,190	15,377
Unilateral Free TRAM	7	11.8	7.7	4,387	26,984
Unilat Pedicle TRAM	19	8.4	5.5	3,208	17,406

Group	<i>n</i>	Ratios of Resources Used ³			
		OR Hours	Inpt Days	UM RVUs	Charges
Bilateral implant	1	2.1	4.1	2.4	2.1
Bilateral Free TRAM	1	2.7	4.7	2.2	1.7
Bilateral Pedicle TRAM	2	2.5	4.1	2.2	2.1
Unilateral implant	6	1.0	1.0	1.0	1.0
Unilateral Free TRAM	7	2.1	4.5	2.0	1.8
Unilat Pedicle TRAM	19	1.5	3.2	1.5	1.1

¹UM RVUs include OR hours, recovery room hours, and length of stay.

²Charges include everything (total hospital bill) except professional services.

³Ratio data: Unilateral implant is set at 1.0; resource use for other procedures is measured relative to this amount.

Regarding our effort to identify an appropriate conversion factor for translating professional charges into RVUs, we have decided to use Medicare RBRVS (Resource Based Relative Value Scale) costs for professional services for 1992, the same year in which the UM RVUs were developed.

In addition to assigning UM RVUs to hospital services, we will perform three additional financial analyses. The objectives of the additional analyses are to: (1) ensure widespread acceptability of our analyses (not everyone will necessarily accept RVUs developed by the University of Michigan as an accurate measure of resource utilization); (2) allow the analysis of professional and hospital costs *combined*, which is difficult using the UM RVU system; and (3) conduct a sensitivity analysis of alternative measures of costs, which may be useful to other researchers. The three additional analyses are described below:

Reimbursement rates: One of the major objectives of this research is to provide information to payers that will help determine which treatments should be reimbursed. To this end, financial data on relative reimbursement rates of alternative procedures are as useful as cost data. Therefore, we are obtaining data on expected or actual reimbursement rates from the participating hospitals and physicians.

Actual charges: It is generally recognized that charges are a very poor measure of costs, because of the lack of standardization across hospitals in the relationship of costs to charges. Nevertheless, charge data are the easiest and most comprehensive financial data to obtain from hospitals and physicians; and although the absolute charges are not likely to have much relationship to actual costs, it is possible that the ratio of charges among the procedures of interest may be similar to the ratio of costs. Therefore, we plan to analyze charge data for all study patients. We will compare the ratio of charges for the different procedures to the ratio of reimbursement rates and ratio of RVUs, to see if the results are similar.

Resource utilization: Because clinicians, payers, administrators, and other researchers may find fault with one or more of our assumptions in our analyses of RVU, reimbursement, and charge data, we are also collecting data on the major resources used in breast reconstruction treatment: length of inpatient stay, operating room time, and recovery room time. Some of our participating hospitals provide these data on the bills we are obtaining; for other hospitals we are collecting these data as part of our chart reviews. Thus far we have collected resource data on 207 patients. After we analyze the data and present descriptive results for each of the different procedures, other facilities or payers can calculate their own costs by multiplying each unit of resource use by the unit cost figure of their choice.

E. Conduct aesthetic evaluations (surgeon evaluator ratings, and anthropometric assessments) of patients.

At the end of the two year study period, we request that the referring physician take a set of photos of the study participants. To date we have received photos on 106 patients. Each photo has been converted to a digital image using a computer equipped with a Nikon Coolscan transparency scanner. Image analysis software is used to compute breast symmetry indices for

each patient. Analysis of the breast symmetry will allow for objective comparison of reconstructive results obtained with different surgical techniques.

Surgeon evaluator ratings will be completed at the end of the study. At that time, the postoperative photographs will be submitted to a panel consisting of three UM staff plastic surgeons who have not been involved with the care of any MBROS patients. Overall aesthetic outcomes will be rated by each evaluator using a modification of the Garbay, et al. rating system which is a composite of five subscales including breast volume, contour, mound placement, scar, and inframammary fold.

Patients' subjective assessments are measured by their responses to a set of questions regarding their satisfaction with the aesthetic results of breast reconstruction. These questions are included in the post-surgery evaluation form.

We have completed a preliminary analysis of the post-operative photos obtained from 84 patients who had undergone breast reconstruction following mastectomy. Breast symmetry was evaluated using 21 standard anthropometric breast measurements derived from Penn (1955) and Smith (1986). Using objective measures of aesthetic outcome, we found that for all measured groups, transverse rectus abdominis musculocutaneous (TRAM) flap reconstruction offered superior dimensional symmetry over implant reconstruction. An abstract describing this work has been accepted for presentation at the annual meeting of the American Society of Plastic and Reconstructive Surgeons and is included as attachment six.

E. Perform Data Analysis

Preliminary analyses of psychosocial, functional and patient satisfaction outcomes have been completed. Data analysis is ongoing and will continue throughout the next several years. To date we have published four manuscripts and two abstracts in peer reviewed journals. An additional manuscript in press, two have been submitted for publication and another is in the final stages of preparation. We have presented study results at 20 professional meetings.

KEY RESEARCH ACCOMPLISHMENTS

- Developed a data set that includes 1,394 fields of data for each patient on psychosocial outcomes functional outcomes, complications, costs, and aesthetic results of breast reconstruction
- Collected isokinetic data that provides an objective, quantitative and reliable measure to evaluate abdominal muscle strength pre- and post-surgery
- Collected standardized photos of over 100 subjects that have been converted to digital images for objective analysis of the aesthetic outcomes of breast reconstruction.
- Preliminary data has been presented at 20 professional meetings
- Six articles or abstracts have been published, one is in press and two have just been submitted for publication
- Developed an educational web site for breast reconstruction patients that includes results from the *Michigan Breast Reconstruction Outcome Study*.

- Key Research Conclusions:
 - Psychosocial Outcomes:
 - There are measurable gains in psychosocial well-being for all patients undergoing breast reconstruction with minimal differences between the various types of reconstruction in psychosocial outcomes.
 - Functional Outcomes:
 - As compared with implant techniques, both pedicle and free TRAM breast reconstructions may result in objectively measurable declines in abdominal wall function. However, these functional changes are not reflected in patients' subjective assessments of their abilities to perform routine activities of daily living. Furthermore, as indicated by both isokinetic testing and questionnaire results, free TRAMs may not offer relative functional advantages over pedicle TRAMs.
 - Patient Satisfaction
 - General Satisfaction - Women choosing TRAM flaps were significantly more generally satisfied with their reconstruction compared with tissue expander/implant patients. There was no significant difference in general satisfaction between women receiving free and pedicle TRAM reconstructions. Furthermore, more active women expressed greater general satisfaction with reconstruction. Procedure timing and patient age had no significant effects on satisfaction.
 - Aesthetic Outcomes - TRAM patients were significantly more satisfied with the aesthetic results of reconstruction than women undergoing expander/implant reconstruction. Furthermore, patients receiving pedicle TRAM reconstructions were more aesthetically satisfied than those choosing free TRAM flaps.
 - Quality of Life and Affective Distress
 - In a comparison of the psychosocial and functional status of women undergoing immediate reconstruction versus delayed reconstruction, patients undergoing immediate reconstruction experienced a relatively high incidence of psychosocial and functional distress.
 - Complications
 - In an analysis of complication rates and patient satisfaction among breast cancer patients treated with mastectomy and a tissue expander/implant with and without radiotherapy, we found that irradiated patients had a higher rate of reconstruction failure and complications than non-irradiated patients. Despite these differences, our pilot data suggests that both general satisfaction and patient aesthetic satisfaction were not significantly different following radiotherapy compared to patients who did not receive radiotherapy.
 - Aesthetic Outcomes
 - Using objective measures of aesthetic outcome, we found that for all measured groups, TRAM flaps offered superior dimensional symmetry over implant reconstructions. Furthermore, pedicle TRAM reconstructions produced greater symmetry than free TRAM flaps in all measured groups.

REPORTABLE OUTCOMES

Please see the following attachments:

- Attachment one:** Presentations and Publications
- Attachment two:** Manuscript: "A Prospective Analysis of Psychosocial Outcomes of Postmastectomy Breast Reconstruction: Preliminary Results From The Michigan Breast Reconstruction Outcome Study", submitted to *Plastic and Reconstructive Surgery*, August, 1999.
- Attachment three:** Manuscript: "Implementation of a Clinical Pathway for TRAM Breast Reconstruction". In press, *Plastic and Reconstructive Surgery*.
- Attachment four:** Manuscript: "Determinants of Patient Satisfaction in Post-Mastectomy Breast Reconstruction". Submitted to *Plastic and Reconstructive Surgery*.
- Attachment five:** Abstract: "Quality of Life and Affective Distress in Women Seeking Reconstruction for Breast Cancer". Presented at The Society of Behavioral Medicine, Twentieth Annual Scientific Session, San Diego, CA, March 3-6, 1999.
- Attachment six:** Abstract: "Determinants of Patient Satisfaction in Post-Mastectomy Breast Reconstruction", American Association of Plastic Surgeons, 78th Annual Meeting, Colorado Springs, Colorado, May 1-5, 1999.
- Attachment seven:** Abstract: "Objective Assessment of Aesthetic Outcomes in Breast Reconstruction". American Society of Plastic and Reconstructive Surgeons, Annual Meeting, New Orleans, Louisiana, October 26, 1999.
- Attachment eight:** Abstract: "Complications and Patient Satisfaction Following Breast Implant Reconstruction With and Without Radiotherapy". American Society for Therapeutic Radiation Oncology, Annual Meeting, San Antonio, Texas, November 3, 1999.
- Attachment nine:** Printed copy of the new University of Michigan Breast Reconstruction Educational web site that includes data from the *Michigan Breast Reconstruction Outcome Study*

CONCLUSIONS

As noted above, final results for the Michigan Breast Reconstruction Outcome Study (MBROS) have yet to be reported pending completion of final data collection and analysis in Spring of 2000. However, the early results detailed above, are providing patients and providers with important insights to assist in treatment decision making for post mastectomy breast reconstruction. For example, the MBROS analysis of functional outcomes and reconstruction revealed heretofore unreported postoperative functional deficits in abdominal wall function for

TRAM flap patients. In light of these findings, our group is now developing pre- and postoperative rehabilitation interventions to prevent or ameliorate postoperative deficits in this patient population.

Study results on psychosocial outcomes have also provided new information. Because these outcomes reflect results, which are most important to patients (i.e., well being, quality of life, and health status), the results of this analysis also provide important insights to assist in medical decision making. Specifically, we have noted that patients undergoing immediate reconstruction following mastectomy realize significant gains in multiple psychosocial parameters, regardless of procedure type. By contrast, in our delayed reconstruction group, important procedural differences were observed. (Please refer to the enclosed appendices for further details.)

The projects' recent assessment of patient satisfaction outcomes also provides key information to assist patients in making difficult reconstructive decisions. Although women undergoing TRAM flaps incur longer procedures, hospitalizations, and recoveries, these patients also report the highest levels of aesthetic and general satisfaction, compared with women receiving implant reconstructions. Despite these procedural differences, however, the majority of women undergoing reconstruction appear relatively satisfied with their choices, regardless of reconstructive procedures.

While the outcome data summarized above may prove valuable in helping surgeons and their patients in making appropriate treatment choices, MBROS investigators acknowledge the remaining challenge of conveying this information in an effective and understandable format to professional and lay consumers. As noted in this report, considerable effort has been devoted to disseminating these data via presentations at national meetings. Furthermore, as study analyses progress and additional data are collected, MBROS investigators are active in publication of their results. Dissemination of study results to consumers posed a more difficult problem. To address this issue, we have devoted considerable effort to the development of a web site modeled on the shared decision making programs, (SMP), produced by the foundation for shared medical decision making. In the MBROS web site, patients receive information on the pros and cons of reconstruction, reconstructive procedures, and non-surgical alternatives. Information drawn from MBROS as well as other outcome studies in the peer reviewed literature serve as sources of information. Considerable care has been taken to create a format, which is easily understood by patients with at least a fourth grade education level. In addition, both artist renditions and patient photographs are used to help patients understand the technical aspects and potential results of reconstruction. Finally, written accounts by individual patients, who have undergone the various reconstructive options, are also included. These accounts are quite realistic in describing both the benefits and risks of reconstruction. A beta version of the web site is currently being tested in a clinical setting at the University of Michigan. Following completion of final revisions, this web site will be made available nationwide to patients and providers. In essence, our goal for the web site is to provide up to date outcome information to those who need it most – i.e., consumers facing difficult reconstructive decisions.

**Michigan Breast Reconstruction Outcome Study,
DAMD 17-94-4044**

**Annual Report
September 16, 1999**

ATTACHMENT ONE

**PRESENTATIONS AND
PUBLICATIONS**

Attachment One

MICHIGAN BREAST RECONSTRUCTION OUTCOME STUDY

September 15, 1999

PRESENTATIONS

- Wilkins EG, "Update on the Michigan Breast Reconstruction Outcome Study": Breast Surgery in the Nineties. Symposium Sponsored by the Plastic Surgery Educational Foundation. January, 1995, Atlanta, Georgia
- Wilkins EG, "Outcomes Research in Breast Surgery": Breast Surgery in the Nineties. Symposium Sponsored by the Plastic Surgery Educational Foundation. January, 1995, Atlanta, Georgia
- Wilkins EG, "Analysis of Instruments for Assessment of Aesthetic Outcomes in Breast Reconstruction." 11th Annual Plastic Surgery Educational Foundation, Breast Surgery Symposium. Atlanta, Georgia, January, 1995.
- Wilkins EG, "Outcomes Research in Breast Surgery." 11th Annual Plastic Surgery Educational Foundation Breast Surgery Symposium. Atlanta, Georgia, January, 1995.
- Wilkins EG, "Update on the Michigan Breast Reconstruction Outcome Study (MBROS)." 12th Annual Plastic Surgery Educational Foundation, Breast Surgery Symposium, Atlanta, Georgia, January, 1996.
- Wilkins EG, "Outcomes Research in Breast Surgery." 12th Annual Plastic Surgery Educational Foundation, Breast Surgery Symposium. Atlanta, Georgia, January, 1996.
- Wilkins EG, "Comparisons of Functional Outcomes in Post Mastectomy Breast Reconstruction." 1997 Arkansas Plastic Surgery Symposium, Stuttgart, Arkansas, December, 1996.
- Wilkins EG, "Comparisons of Functional Outcomes in Post Mastectomy Breast Reconstruction." Plastic Surgery Research Council. 42nd Annual Meeting, Galveston, Texas, February, 1997.
- Cederna PS, "A Prospective Analysis of the Psychosocial Effects of Postmastectomy Breast Reconstruction." 1997 Plastic Surgery Senior Residents Conference, Sacramento, California, April, 1997. Awarded *Best Scientific Paper* for Senior Residents Conference.
- Wilkins EG, "Functional Outcomes in Post-Mastectomy Breast Reconstruction." American Association of Plastic Surgeons. 76th Annual Meeting, Portland, Oregon, May 20, 1997.
- Wilkins EG, "The Outcome Analysis of Breast Reconstruction, The Michigan Experience." World Congress of Surgeons, Annual Symposium, Acapulco, Mexico, August 28, 1997.
- Cederna PS, "Michigan Breast Reconstruction Outcome Study: Prospective analysis of the psychosocial outcomes of autogenous tissue versus implant breast reconstruction, ASPRS/PSEF/ASRM Annual Scientific Meeting, September 20-24, 1997, San Francisco, CA

- Cederna PS, "Prospective Analysis of Psychosocial Outcomes in Postmastectomy Breast Reconstruction." American College of Surgeons Annual Clinical Congress, Chicago, Illinois, October, 1997.
- Wilkins EG, "Functional Outcomes in Post-Mastectomy Breast Reconstruction: Preliminary Results of the Michigan Breast Reconstruction Outcome Study." American College of Surgeons Annual Clinical Congress, Chicago, Illinois, October, 1997
- Cederna PS, "Computerized Assessment of Aesthetic Outcomes in Breast Reconstruction: Determination of Breast Volume." Plastic Surgery Research Council, 43rd Annual Meeting, Loma Linda, California, April, 1998
- Alderman, A, "Determinants of Patient Satisfaction in post-Mastectomy Breast Reconstruction." Michigan Academy of Plastic Surgeons, 1998 Summer Scientific Meeting, Mackinaw Island, Michigan, July 12 -15, 1998
- Roth, RS, "Quality of Life and Affective Distress in Women Seeking Reconstruction for Breast Cancer", The Society of Behavioral Medicine, Twentieth Annual Scientific Session, San Diego, CA, March 3 - 6, 1999.
- Wilkins, EG "Determinants of Patient Satisfaction in Post-Mastectomy Breast Reconstruction", American Association of Plastic Surgeons, 78th Annual Meeting, Colorado Springs, Colorado, May 2-5, 1999.
- Kreiger, E "Complications and Patient Satisfaction Following Breast Implant Reconstruction With and Without Radiotherapy". American Society for Therapeutic Radiation Oncology Annual Meeting, San Antonio, Texas, November 3, 1999.
- Reynolds, J "Objective Assessment of Aesthetic Outcomes in Breast Reconstruction". American society of Plastic and Reconstructive Surgeons Annual Meeting, New Orleans, Louisiana, October 26, 1999.

PUBLICATIONS

ABSTRACTS

Cederna PS. Wilkins EG. Lowery JC. Goldfarb SL. Perkins AJ. Prospective analysis of psychosocial outcomes in postmastectomy breast reconstruction. 83rd Annual Clinical Congress of the American College of Surgeons, Surgical Forum, Volume XLVIII, October 1997, pp. 607-609.

Wilkins EG. Lowery JC. Kuzon WM. Perkins AJ. Functional Outcomes in Post-Mastectomy Breast Reconstruction: Preliminary Results of the Michigan Breast Reconstruction Outcome Study. 83rd Annual Clinical Congress of the American College of Surgeons, Surgical Forum, Volume XLVIII, October 1997, pp 609-612.

Cederna PS, Wilkins EG, Lowery, JC, Goldfarb S, Perkins A. The Michigan Breast Reconstruction Outcome Study: Prospective analysis of the psychosocial outcomes of breast reconstruction. 66th Annual Scientific Meeting of the American Society of Plastic and Reconstructive Surgery, Plastic Surgical Forum, Volume 20, September, 1997, pp. 168-70.

PUBLICATIONS, CONT

MANUSCRIPTS:

Lowery JC. Wilkins EG, Kuzon WM. Davis JA.. Evaluations of aesthetic results in breast reconstruction: an analysis of reliability. *Annals of Plastic Surgery* 36(6):601-6; discussion 607, 1996, Jun.

Wilkins EG. Lowery JC. Smith DJ Jr. Outcomes research: a primer for plastic surgeons. *Annals of Plastic Surgery* . 37(1):1-11, 1996, Jul.

Segar ME. Katch VL. Roth RS. Garcia AW. Portner TI, Glickman SG. Haslanger S. Wilkins EG. The effect of aerobic exercise on self-esteem and depressive anxiety symptoms among breast cancer survivors. *Oncology Nursing Forum*., 25(1):107-13, 1998 Jan-Feb..

Manuscripts Submitted:

Hwang TG. Wilkins EG. Lowery JC. Gentile JA. Implementation of a Clinical Pathway for TRAM Breast Reconstruction. In press, *Plastic and Reconstructive Surgery*.

Cederna PS. Lowery JC. Davis JA, Hyungjin MK. Roth RS. Goldfarb SL. Wilkins EG. A Prospective Analysis of the Psychosocial Outcomes of Postmastectomy Breast Reconstruction: Preliminary Results from the Michigan Breast Reconstruction Outcome Study. Submitted to *Plastic and Reconstructive Surgery*, August, 1999.

Alderman AK, Wilkins EG, Lowery JC, Hyungjin MK. Determinants of Patient Satisfaction in Post-Mastectomy Breast Reconstruction. Submitted to *Plastic and Reconstructive Surgery*, August, 1999.

Manuscripts In Preparation:

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Attachment Two
Michigan Breast Reconstruction Outcome Study
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A Prospective Analysis of the Psychosocial Outcomes of Postmastectomy Breast Reconstruction: Preliminary Results From The Michigan Breast Reconstruction Outcome Study

Paul S. Cederna, MD¹, Julie C. Lowery, PhD^{1,2}, Jennifer A. Davis, MHA², Hyungjin Myra Kim, ScD^{2,3}, Randy S. Roth, PhD⁴, Sherry Goldfarb, MPH¹,
Edwin G. Wilkins, MD^{1,2}
Ann Arbor, Michigan.

1Section of Plastic and Reconstructive Surgery, University of Michigan Health Systems, Ann Arbor, MI
2Veterans Affairs Center for Practice Management and Outcomes Research, Ann Arbor, MI
3Department of Biostatistics, University of Michigan, Ann Arbor, MI
4Departments of Physical Medicine and Rehabilitation and Anesthesiology, University of Michigan, Ann Arbor, MI

Corresponding Author: Paul S. Cederna, M.D.
University of Michigan Health Systems
Section of Plastic and Reconstructive Surgery
2130 Taubman Center, 1500 East Medical Center Drive
Ann Arbor, MI 48109-0340
Telephone: 734-936-5895
Fax: 734-763-5354
e-mail: cederna@umich.edu

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Abstract

Context.- Over 40,000 postmastectomy breast reconstructions are performed annually in the United States. The psychosocial benefits of breast reconstruction have been demonstrated in previous reports, but very little information is available comparing the psychosocial outcomes for the various surgical options in breast reconstruction.

Objective.- To determine if psychosocial outcomes of breast reconstruction differ by type of surgical procedure.

Design.- Data were prospectively collected from patients undergoing postmastectomy breast reconstruction preoperatively and one year postoperatively.

Setting.- 12 institutions in the United States and Canada with 24 plastic surgeons.

Subjects.-Patients requesting immediate or delayed postmastectomy breast reconstruction utilizing a tissue expander/implant, pedicle TRAM flap, or free TRAM flap.

Main Outcome Measure.-Difference between postoperative and preoperative responses to Medical Outcome Study-Short Form (SF-36) subscales (general mental health, emotional well-being, and vitality), Functional Assessment of Cancer Therapy-Breast (FACT-B) functional well-being subscale, and condition specific breast scale.

Results.-Patients in all three surgical groups experienced a significant increase postoperatively in general mental health, emotional well-being, and functional well-being; no significant differences between groups were identified. Patients undergoing delayed tissue expander/implant reconstruction experienced a significantly greater increase in vitality, but a significantly smaller increase in satisfaction with aesthetic results, than patients undergoing delayed TRAM procedures. No difference in the increase in vitality or aesthetic satisfaction was observed between surgical groups for patients undergoing immediate reconstruction.

Conclusions.-This analysis suggests that there are measurable gains in psychosocial well-being for all patients undergoing breast reconstruction and that minimal differences are identified between the various procedure types in the measured outcomes.

Introduction

During the past 25 years, the psychological adaptation of women undergoing mastectomy as treatment for breast cancer has been extensively studied (1). Early reports describe a wide range of lasting psychological disturbances including disruption of body image, severe depression, and feelings of diminished self-worth (2-10). More recently, numerous studies have more completely defined the psychosocial sequelae of mastectomy across several psychological parameters including: loss of femininity (11,12); mood disturbances (13); and interpersonal, sexual and marital dysfunction (14-17).

It has been suggested that breast reconstruction may be equivalent to a "reverse mastectomy" (6), offering the most effective means for restoration of a woman's psychological well-being following mastectomy (18). In the past decade, changing attitudes toward breast reconstruction among both patients and providers have led a growing number of women to seek breast reconstruction following mastectomy for cancer (19). As a result, the psychological adjustment of women who choose to undergo post-mastectomy breast reconstruction has become the focus of considerable research. A number of studies have documented the psychological, social, emotional, cosmetic, and functional benefits of breast reconstruction, including improved psychological health (20-22), self esteem, sexuality, and body image (6, 10, 20, 22-31), and reduced concerns of cancer recurrence (20).

However, no study has *prospectively* compared the psychosocial outcomes of patients undergoing tissue expander/implant versus transverse rectus abdominis myocutaneous (TRAM) flap breast reconstruction. In 1996 (the most recent year for which data are available), expander/implant techniques constituted 48% of all procedures for breast reconstruction (32). However, growing concerns within the scientific and lay communities over the long-term safety of implants has sparked increasing interest in breast reconstruction techniques utilizing autogenous (natural) tissue; TRAM flap procedures constituted 30% of all breast reconstruction procedures in 1996. Each of these procedures is described below.

Use of a silicone gel or saline implant for reconstruction of the breast mound is frequently preceded by a preliminary operation in which a temporary tissue expander is inserted. In the first stage of this two-step reconstruction, a pocket is created in the subcutaneous or submuscular (subpectoral) plane at the site of the mastectomy. The expander is inserted into this space and the overlying layers are closed. Initially resembling a deflated balloon, the tissue expander is serially inflated with weekly postoperative percutaneous injections of sterile saline solution via a port in the front wall of the device. The gradually enlarging expander induces both stretch and growth in the overlying skin and muscle. Ultimately, with the creation of an adequately-sized implant pocket and sufficient new soft tissue coverage, the second stage of the reconstruction is carried out: the tissue expander is removed and replaced by a silicone gel or saline prosthesis. For purposes of this study, patients who underwent the expander-implant reconstruction procedure and those who received implants without expanders are included in the same group, "expander/implant."

Described by Hartrampf in 1983 (33), conventional TRAM flap reconstruction consists of a pedicled rectus abdominis muscle flap which is elevated in continuity with an overlying island of lower abdominal skin and fat. While the superior end of the muscle carrying the blood supply remains attached to the abdominal wall, the lower rectus muscle segment and skin island are tunneled superiorly into the mastectomy site. The TRAM flap is then sculpted and inset to produce optimal symmetry with the contralateral breast. The abdominal donor site is closed as an abdominoplasty.

More recently Grotting has described a TRAM "free flap" (34). In this variation, a smaller segment of rectus muscle is used as a carrier for the same island of overlying abdominal skin and fat. During flap mobilization, the muscle's lower vascular supply, the deep inferior epigastric artery and vein, is harvested in continuity with the muscle segment and skin island. The flap is dissected completely free from its donor site and transferred to the mastectomy wound. Blood supply to the flap is reestablished by microsurgically anastomosing its vascular pedicle to the thoracodorsal artery and vein in the axilla.

Performed either as a pedicle flap or as a free tissue transfer, the TRAM flap provides both soft tissue coverage and bulk for the new breast without the use of an implant. In addition, proponents of the TRAM flap have claimed aesthetically superior results to implants, with the free TRAM offering additional advantages of improved flap survival, better contour, and preservation of abdominal wall function.

However, despite the advantages that TRAM flaps may offer over implant reconstruction, autogenous tissue methods are technically more difficult procedures, with reported complication rates ranging from 3 percent (35) to 66 percent (36). Although the general trend in reconstruction is toward the use of autogenous tissue and away from prosthetic implants, the advantages of natural tissue techniques have not been clearly demonstrated. Therefore, the purpose of our investigation was to perform a comprehensive prospective analysis of potential differences in psychosocial effects of the three different breast reconstruction techniques (tissue expander/implant, pedicle TRAM flap, and free TRAM flap) through validated, self-assessment instruments. We hypothesize that there is no difference in the psychosocial outcomes between tissue expander/implant versus TRAM flap breast reconstruction.

Methods

As part of the Michigan Breast Reconstruction Outcome Study (MBROS), cohorts of patients undergoing immediate or delayed postmastectomy breast reconstruction at one of 12 institutions in the United States and Canada were enrolled. Unilateral or bilateral reconstructions were performed by one of 24 participating plastic surgeons. The timing of reconstruction, immediate versus delayed, was determined by the patient after discussions with the surgical oncologists and the plastic surgeons. Study groups included women receiving tissue expander/implant, pedicle TRAM flap, or free TRAM flap breast reconstructions for their primary reconstruction. Women who required secondary reconstructive procedures like TRAM flap revision, who had not previously been enrolled, were excluded from entry into the study, due to the potential for introducing confounding independent variables. Individuals with absolute contraindications to one of the reconstructive procedures were also excluded from the study, because these patients did not have the option of choosing between the various procedure types.

At the time of their recruitment, potential participants were provided with a complete information package which discussed the purpose and objectives of the study, the responsibilities of the patients who agree to participate, and an informed consent form. Once the decision to undergo breast reconstruction was made and the subject's participation in the study was secured, a take-home battery of previously validated self-assessment questionnaires was given to the patient, to be completed during the 2 week period prior to their breast reconstruction. The questionnaire was returned by mail to the study coordinator.

One year postoperatively, the patients were notified by telephone regarding the impending receipt of follow-up questionnaires to be completed on their one year anniversary. All sociodemographic and medical information was updated at this time. The one year postoperative questionnaires contained the same items as the preoperative questionnaire. In addition, seven questions were included to evaluate satisfaction with surgery. Once again, questionnaires were completed at home and returned to the study coordinator by mail.

Withdrawal from the study was considered for one of 8 reasons; 1) incomplete preoperative questionnaires; 2) comorbid problems preventing completion of study; 3) patient decision to discontinue participation; 4) cancellation of surgery; 5) cancer recurrence; and 6) patient death. The experimental protocol was approved by the institutional review boards for all participating medical centers.

Psychometric Battery of Questions

The study instruments were selected to ensure that a sufficiently broad range of variables was measured to describe the psychological and functional status of the

postmastectomy reconstruction patient. The preoperative and postoperative questionnaires required 60 to 90 minutes each to complete. The use of patient self-report measures is consistent with the growing emphasis in outcomes research on patient satisfaction (37), quality of life, and general well-being (38, 39) in evaluating quality of care. We supplemented these generic measures of health status with condition-specific instruments to further develop a multifactorial profile of the patient population and to enhance the potential to discriminate among outcomes produced by the various types of surgical procedures (40, 41). Lastly, we selected reliable, validated assessment tools which have established credibility in the scientific literature and have been previously used in cancer treatment outcome studies. A brief description of the psychometric battery is listed below:

Medical Outcome Study-Short Form (SF-36):

The SF-36 is a 36 item, self-administered, validated questionnaire which has been widely used in a variety of health care settings to evaluate symptom change and treatment outcomes for patients receiving medical interventions (40, 42, 43). This generic measure of health status consists of the following eight subscales: physical functioning, role limitations due to physical problems, role limitations due to emotional problems, bodily pain, vitality, social functioning, mental health, and general health. For purposes of describing patients' psychosocial status in our study, we analyzed data from the role-emotional, vitality, and mental health subscales. The specific questions that make up these subscales are presented in Table 1.

Responses to both the vitality and mental health subscales range from 1 to 6, with 1 representing "all of the time" and 6 representing "none of the time." Possible responses to the role-emotional subscale are "yes" or "no." Responses to all questions were scored in the database such that higher scores represent higher psychosocial well being (i.e., fewer problems). Scores for each subscale were summed and then transformed to a scale from 1 to 100 (to facilitate comparison of scores across subscales).

Functional Assessment of Cancer Therapy- Breast (FACT-B):

The FACT-B is a condition-specific instrument which measures the health status of breast cancer patients and includes the following subscales: physical well-being, social well-being, relationship with doctor, emotional well-being, functional well-being, and additional concerns. The questions best representing a patient's overall psychosocial status are those in the functional well-being subscale, and are shown in Table 2 (44, 45).

All responses to FACT-B questions range from 0 to 4, with 0 representing "not at all" and 4 representing "very much." Responses were scored in the database such that higher scores represent greater satisfaction. In the functional well-being subscale, scores for the seven questions were summed to get an overall score for the subscale; thus, total possible scores range from 0 to 28.

Condition-Specific Items:

The additional condition-specific questionnaire was designed to evaluate the patient's perception of their physical appearance (Table 3). These items were not taken from a previously validated instrument and as a result, it is unclear to what extent these questions represent a single construct (physical appearance), and should be scored as a single scale; or whether they represent multiple constructs and should be scored as separate subscales. Therefore, Cronbach's alpha was calculated for various combinations of questions to determine which questions have the largest correlations among each other. For example, do the questions, "I feel whole," "I feel attractive," and "I think of my cancer when I look at my breasts," represent a distinctly different "emotional" assessment of one's appearance than the remaining six questions? Results of the analysis showed that the largest Cronbach's alpha (0.8950) is achieved when all questions are combined into a single scale.

Therefore, a new condition-specific scale was developed for this study consisting of all of the questions listed in Table 3. Responses to each question ranged from 1 to 5, with 1 representing "definitely true" and 5 representing "definitely false." Responses were scored in the database such that 5 always represented the most positive attitude. The scores for all nine questions were summed to determine a total score for the scale; thus, the total possible scores

range from 9 to 45, with high scores indicating a more positive assessment of one's physical appearance.

Statistical Analysis

The outcomes of interest are the "change scores" for each of the scales described above, where "change score" refers to the post-surgery score minus the pre-surgery score. Because higher scores represent more positive attitudes in all of the above scales, a positive change score indicates an improvement from pre-surgery to post-surgery. Change scores are more accurate measures of surgical outcomes than postoperative scores, because they reflect the patient's status prior to surgery. For example, two groups of patients can end up with the same postoperative scores, but one group may have started out with much lower preoperative scores. Thus, the group with the larger change in scores has experienced greater improvement, and, therefore, may be considered to have better outcomes. Hence, it is important to validate the results of previous research efforts, which have relied primarily on postoperative results alone, with prospective studies that collect both pre- and postoperative data.

The overall objective of the analyses was to determine if the magnitude of change between pre- and post-surgery varies by procedure type, while controlling for other variables that (1) may be associated with the outcomes *and* (2) are distributed unequally across procedure type. Therefore, the first set of analyses identified those additional independent variables that should be included in the analysis of the relationship between procedure type and outcomes.

Chi-square analysis was used to examine if the percentage distribution of various demographic variables was significantly different across procedure type. The demographic variables included in this analysis were: marital status, level of education, race, income, employment status. None of these variables was significantly associated with procedure type; so, these variables were not included in subsequent analyses. Analysis of variance (ANOVA) was used to determine if age was significantly associated with procedure type. Results, which are presented in Table 4, showed that age is nearly significant at $p = 0.087$. Therefore, age was included as an independent variable in subsequent analyses of the effects of procedure type on psychosocial outcomes.

In addition to demographic variables, the pre-surgery scores from each of the psychosocial scales are likely to influence the change scores, according to a "regression to the mean" effect. That is, those patients who start out lower on the scales are likely to experience a greater increase than those who start out with higher scores. Therefore, pre-surgery score was also included as an independent variable in the analyses.

Finally, timing of reconstruction is also likely to have an effect on the outcomes measured. Table 5 depicts the percentage distribution of procedure types based upon the procedure timing. The results show that in our sample, implant patients had a greater percentage of immediate reconstructions than did TRAMs, and free TRAMs had a greater percentage than did pedicle TRAMs (significant at $p=0.013$). Therefore, reconstruction timing was included as an independent variable in the analysis.

In reviewing the content of the psychosocial scales, one would hypothesize a significant relationship between timing of reconstruction and some of the pre-surgery scores. Specifically, patients undergoing immediate reconstruction are dealing with the issue of a very recent breast cancer diagnosis at the same time they are responding to the study questionnaire. Therefore, it is likely that their pre-surgery scores on questions dealing with emotional well-being will be much lower than patients undergoing delayed reconstruction, who have had more time to adjust to their cancer diagnosis. In addition, patients undergoing delayed reconstruction are likely to provide more negative responses to the condition-specific breast questions, because they only have one (or no) breasts when they are completing the pre-surgery questionnaire. These hypotheses are indeed supported by *t*-tests of the differences in pre-surgery scores between immediate and delayed patients, as shown in Table 6. The results show that immediate and delayed patients are significantly different on pre-surgery scores for all of the scales. Given the large discrepancy in pre-surgery scores between patients undergoing immediate versus delayed

reconstruction, and the complexity of understanding the effects of interactions between timing and pre-surgery scores on the measured outcomes, we decided to perform separate analyses for immediate and delayed patients. Thus, the final analyses consisted of analysis of covariance (ANCOVA), conducted separately for patients with immediate and delayed reconstruction; the dependent variables were the change scores, and the independent variables were procedure type, pre-surgery score, and age.

Results

Demographics

287 patients fulfilled the criteria for entry into the study, with complete preoperative and one year postoperative data available from 250 patients (14.8% withdrawal rate). Of women participating in the project, 161 underwent immediate reconstruction and 89 received delayed reconstructions. The implant, pedicle TRAM, and free TRAM flap groups contained 56, 128, and 66 patients, respectively (Table 5). The mean age of patients undergoing postmastectomy breast reconstruction in each group was not significantly different (Table 4). No statistically significant differences in employment status, marital status, ethnicity, level of education, or income level were identified between the groups.

All Breast Reconstruction Patients

All breast reconstruction patients noted statistically significant gains in psychosocial well-being one year postoperatively, as compared to their preoperative status. Increased scores were identified in general mental health, emotional well-being, vitality, functional well-being, and aesthetic satisfaction (condition-specific scale), as presented in Table 7. A detailed description of differences among procedures within each of the scales is provided below.

SF-36

General Mental Health Subscale:

A statistically significant increase in general mental health status was identified in all patients undergoing immediate or delayed breast reconstruction, utilizing free TRAM flaps, pedicle TRAM flaps, or tissue expander/implant reconstructions. Preoperatively, the immediate reconstruction patients had lower scores for general mental health. No significant differences in change in general mental health status were identified between the surgical groups within each timing category (immediate and delayed) (Figure 1).

Role Emotional Subscale

A statistically significant increase in the role emotional subscale scores was identified in all patients undergoing breast reconstruction, regardless of the procedure type or timing. As identified in the general mental health subscale, the immediate reconstruction patients had lower role emotional scores preoperatively than the delayed reconstruction patients. There were no significant differences between surgical groups in the increase between preoperative and postoperative scores (Figure 2).

Vitality Subscale

The vitality of patients undergoing delayed breast reconstruction utilizing a tissue expander/implant increased significantly one year postoperatively as compared to their preoperative status ($p < 0.05$). All other patients remained relatively unchanged during the same time interval (Figure 3).

FACT-B

Functional Well-Being Subscale

Patients electing to undergo immediate reconstruction had significantly lower preoperative scores for functional well-being ($p = 0.012$) than delayed reconstruction patients. There were no statistically significant differences between preoperative and one year postoperative scores based upon procedure type. All groups experienced significant improvements in functional well-being following breast reconstruction (Figure 4).

Condition-Specific Items

Condition-Specific Breast Subscale

Preoperatively, patients undergoing delayed breast reconstruction had significantly lower condition specific breast scores than patients undergoing immediate reconstruction; patients with a surgically absent breast (delayed reconstruction group) were more dissatisfied with their appearance than patients with breasts (immediate reconstruction group). Postoperatively, the delayed reconstruction patients noted dramatic increases in their satisfaction with the aesthetic appearance of their breasts; patients who elected to have a delayed reconstruction utilizing a tissue expander/implant had smaller gains in satisfaction postoperatively than the free and pedicle TRAM flap patients (Figure 5). The immediate reconstruction patients remained relatively unchanged in their scores one year following the reconstruction, with no differences noted between surgical procedures (Figure 1).

All Breast Reconstruction Patients

The psychosocial sequelae of breast cancer and modified radical mastectomy have been comprehensively evaluated in the past and are widely recognized. Negative feelings about body image (5,12,28,46-49), loss of sexuality (12,50-52), loss of self esteem (1,5,53), depression and anxiety (4,6,11,26), and concerns regarding cancer recurrence (10,54,55) have all been well documented. Postmastectomy breast reconstruction has been found to provide innumerable psychosocial benefits including improved body image (20,27,28,30,56), enhanced social functioning (57,58), enhanced feelings of femininity (20,59), and improved sexuality (23,24,36,60).

This prospective analysis utilizing validated, self-assessment instruments supports the previously identified benefits of postmastectomy breast reconstruction of all types. Statistically significant improvements in general mental health, emotional well-being, vitality, and functional well-being were demonstrated in all patients, as compared to their preoperative status.

SF-36

A significant improvement in general mental health status was identified in all patients undergoing breast reconstruction, with no differences between the various procedures types. The immediate breast reconstruction patients had lower preoperative scores; this is a predictable outcome for these patients who were recently diagnosed with breast cancer and are faced with all of the uncertainty of cancer therapy and reconstruction. One year following breast reconstruction, all patients had very similar mental health scores, irrespective of the treatment modality; it is possible that this represents a "regression to the mean" effect. It would be informative to have a control group of mastectomy patients who did not undergo reconstruction, to determine if their scores similarly changed between the preoperative and one year postoperative periods. However, it is unlikely that this patient population would demonstrate statistically significant improvements in mental health during this same time interval, based upon our understanding of the well documented detrimental effects of mastectomy without reconstruction (5,12,28,46-52).

Evaluation of the emotional well-being subscale reveals significant improvements in all patients irrespective of the procedure type or timing. Predictably, the preoperative scores for immediate reconstruction patients were lower than those for delayed patients. As occurred in the general mental health scale, all groups achieved similar gains in emotional well-being one year postoperatively. Both the general mental health and the emotional well-being subscales are nonspecific measures of psychological health, so we would expect no dramatic differences between outcomes for the various procedure types. Nevertheless, if the aesthetic outcome of the breast reconstruction was so poor that the patient became angry, upset, or emotionally disturbed, then we would expect these instruments to detect differences. However, no differences were observed in the aesthetic results (condition specific scale) across the breast reconstruction types within each timing category.

The vitality subscale more specifically addresses the physical issues surrounding the reconstruction and was able to identify more subtle differences between procedure types.

Patients undergoing delayed tissue expander/implant reconstruction reported an increase in vitality with reconstruction and the highest vitality scores of all patients one year postoperatively; all other patients reported no change. The patients requesting immediate reconstruction must undergo combined surgical procedures for tumor extirpation (mastectomy) and breast reconstruction, while potentially requiring adjuvant chemotherapy or radiation therapy. Perhaps the physiologic stress of these required medical and surgical interventions adversely affects the vitality of patients even one year postoperatively. In contrast, the magnitude of surgical procedures for patients requesting delayed breast reconstruction varies significantly based upon procedure type; patients electing TRAM flap reconstruction experience a much greater physiologic stress than tissue expander/implant reconstructions. Apparently, the tissue expander/implant patients experience both the positive effects of the delayed breast reconstruction and a lower physiologic stress based upon the ease with which this operation may be performed, to produce a cumulative increase in vitality. It is theoretically possible that the patients electing tissue expander/implant reconstruction were more "vital" preoperatively, and that is why they elected this form of reconstruction. However, the preoperative vitality scores do not support this theory. If this scale measures a construct closer to physical functioning than to psychological status, the differences measured in vitality one year postoperatively should be less pronounced as the postoperative time period lengthens. In the future, we will be correlating these vitality scores with physical function assessments to more clearly define these outcomes. In addition, we will be obtaining additional data utilizing these instruments each year for a total of two years postoperatively.

FACT-B

The functional well-being subscale is a general mental health scale which is slightly different than the SF-36 because it evaluates the effect of mental health on a patient's everyday functioning rather than simply evaluating a patient's general mental health (44,45). Despite these differences in the measured constructs, no differences in outcomes could be identified based on procedure types or timing. Patients from all groups noted high levels of satisfaction preoperatively, leaving very little room for improvement postoperatively. As expected, the patients in the immediate reconstruction group noted lower scores for functional well-being for reasons previously discussed.

Condition-Specific Breast

Dramatic differences in preoperative condition-specific breast scores were identified between immediate and delayed breast reconstruction patients, with the delayed reconstruction groups having significantly lower scores. This finding is consistent with the previously reported adverse psychosocial sequelae of mastectomy without reconstruction (10, 11, 24, 61-65). Predictably, patients with a surgically absent breast will have lower satisfaction with their physical appearance and reduced feelings of being whole. Postoperatively, the delayed reconstruction patients noted significant improvements in their satisfaction with the aesthetic outcome while the immediate reconstruction patients noted very little change. Immediate reconstruction patients were satisfied with the appearance of their native breasts preoperatively, which provides little room for improvement in satisfaction following breast reconstruction. In addition, it would be difficult to surgically achieve an aesthetic outcome superior to the appearance of the native breast utilizing any reconstructive technique. However, we might have expected these patients to be less satisfied with the appearance of their newly reconstructed breast(s) compared to their preoperative satisfaction, but this was not observed.

A number of studies have performed comparative analyses of the operative times, complications, and costs of free and pedicle TRAM flap breast reconstructions (66-68). However, very little information is available regarding the psychosocial outcomes of these two procedures, especially comparing postoperative to preoperative scores. Our prospective cohort analysis revealed no statistically significant psychosocial or aesthetic outcome differences between these two reconstructive techniques. Based upon the outcomes measured in this study, there were no relative psychosocial advantages to reconstruction by either procedure.

The study design was carefully crafted to provide a large patient population representing many different geographic regions, ethnic backgrounds, educational levels, and races. This multicenter approach will limit the effect of these variables on the study outcomes. In addition, 24 surgeons (listed in the Acknowledgments) enrolled patients in the study and performed breast reconstructions. This group of plastic surgeons is a representative sample of surgeons who routinely perform breast reconstruction. As a result, the outcomes measured are not biased by the surgical skills of a single surgeon, but rather represent results typically achieved by reconstructive surgeons who routinely perform breast reconstruction.

It must be emphasized that this is only a preliminary report evaluating the psychosocial functioning of 250 patients preoperatively and one year postoperatively. Additional information is forthcoming as the study matures and information is prospectively collected one and two years postoperatively. Perhaps we will find that there are significant differences based on procedure types or the timing of reconstruction in psychosocial and aesthetic outcomes two years postoperatively, when more of the tissue expander/implant patients develop capsular contractures or when the TRAM flap patients develop abdominal wall laxity or hernias. These questions will be answered as patients progress through the experimental protocol.

Conclusions

This prospective analysis suggests that there are measurable gains in psychosocial well-being for all groups of patients undergoing breast reconstruction and that minimal differences were identified between the various procedure types in the outcomes measured, even while controlling for age and preoperative scores. Significant differences were identified preoperatively between patients undergoing immediate and delayed breast reconstruction, which can be largely attributed to the psychological stress of a recent breast cancer diagnosis in the immediate reconstruction group. There were also significant differences in the satisfaction with the aesthetic appearance of the breasts preoperatively, which can be accounted for by the surgical absence of a breast in the delayed reconstruction group. There were no differences in postoperative improvements in general mental health, emotional well-being, or functional well-being across procedure type (tissue expander/implant versus TRAM) within timing category (immediate versus delayed). Patients electing to undergo delayed tissue expander/implant breast reconstruction had the lowest increase in satisfaction with the aesthetic appearance of their breast, but had the largest increase in vitality, compared to delayed patients undergoing the other two procedures. All immediate reconstruction patients noted very little change in their vitality or their satisfaction with the aesthetic appearance of their breast postoperatively, regardless of the procedure type. The information provided by this preliminary work should be helpful to reconstructive surgeons as they counsel women preoperatively on their reconstructive options.

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Table 1: Medical Outcome Study Short Form (SF-36): Subscales and Questions

Role-Emotional: During the past four weeks, have you had any of the following problems with your work or other regular daily activities as a result of any emotional problems (such as feeling depressed or anxious)?	
∞	Cut down on the amount of time you spent on work or other activities.
∞	Accomplished less than you would like.
∞	Didn't do work or other activities as carefully as usual.
Vitality: How much of the time during the past four weeks...	
∞	Do you feel full of pep?
∞	Do you have a lot of energy?
∞	Did you feel worn out?
∞	Did you feel tired
Mental Health: How much of the time during the past four weeks...	
∞	Have you been a very nervous person?
∞	Have you felt so down in the dumps that nothing could cheer you up?
∞	Have you felt calm and peaceful?
∞	Have you felt downhearted and blue?
∞	Have you been a happy person?

Table 2: Functional Assessment of Cancer Therapy-Breast (FACT-B):

Functional Well-being Questions

∞	I am able to work (include the work in home).
∞	My work (include work in home) is fulfilling.
∞	I am able to enjoy life.
∞	I have accepted my illness.
∞	I am sleeping well.
∞	I am enjoying the things I usually do for fun.
∞	I am content with the quality of my life right now.

Table 3: Condition-Specific (Breast) Questions

-
-
- ∞ I feel whole.
 - ∞ I like the way my blouses/sweaters fit.
 - ∞ I like the way I look in a bathing suit.
 - ∞ My bra fits comfortably.
 - ∞ I feel attractive.
 - ∞ I think of my cancer when I look at my breasts.
 - ∞ I like the appearance of my breasts.
 - ∞ My significant other likes the appearance of my breasts.
 - ∞ I feel self-conscious during sexual activity because of the appearance of my breasts.
-
-

Table 4: Mean Age by Procedure Type

Procedure	N	Mean	Std. Dev.
Free	67	46.4	9.4
Pedicle	134	49.4	8.7
Implant	61	48.5	9.6

p-value for ANOVA = .0872

where

Free: Free TRAM flap
 Pedicle: Pedicle TRAM flap
 Implant: Tissue expander/implant reconstruction

Table 5: Distribution of Procedure Types by Timing of Procedure

Procedure	Immediate		Delayed		Total	
	N	%	N	%	N	%
Free	42	63.6	24	36.4	66	100.0
Pedicle	74	57.8	54	42.2	128	100.0
Implant	45	80.4	11	19.6	56	100.0
Total	161		89		250	

p-value for chi-square = 0.013

where

Free: Free TRAM flap
 Pedicle: Pedicle TRAM flap
 Implant: Tissue expander/implant reconstruction

Table 6: Pre-Surgery Scores, Immediate vs. Delayed Patients

	Immediate			Delayed			p-value
	N	Mean	S.D.	N	Mean	S.D.	
SF-36 RE	167	60.3	41.1	89	76.8	35.7	0.0015
SF-36 V	167	56.0	21.2	90	61.6	21.6	0.047
SF-36 GMH	167	65.5	19.1	89	73.2	16.9	0.0016
FACT-B Fn	166	20.6	5.2	89	22.2	4.3	0.0127
Breast	165	33.9	6.7	88	20.8	7.8	0.0000

where

SF-36 RE: SF-36 Emotional well-being subscale
 SF-36 V: SF-36 Vitality subscale
 SF-36 GMH: SF-36 General mental health subscale
 Fact-B Fn: FACT-B Functional well-being subscale
 Breast: Condition specific breast subscale

Table 7: Results of Paired t-Test of Preoperative and Postoperative Scores

Scale	N	Preop Score		Postop Score		Mean Difference	p-Value ¹
		Mean	S.D.	Mean	S.D.		
SF-36 RE	268	66.9	39.9	85.1	29.5	18.2	0.0000
SF-36 V	269	58.3	21.6	62.2	20.4	3.8	0.0016
SF-36 GMH	268	68.6	18.6	77.6	16.5	9.1	0.0000
FACT-B Fn	268	21.1	5.0	23.2	4.7	2.0	0.0000
Breast	266	29.1	9.5	34.7	6.9	5.6	0.0000

¹Two sided paired t-test.

where

SF-36 RE: SF-36 Emotional well-being subscale
 SF-36 V: SF-36 Vitality subscale
 SF-36 GMH: SF-36 General mental health subscale
 Fact-B Fn: FACT-B Functional well-being subscale
 Breast: Condition specific breast subscale

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ATTACHMENT THREE

**Manuscript: "Implementation of a Clinical Pathway for
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Implementation and Evaluation of a Clinical Pathway for TRAM

Breast Reconstruction

Taik Gun Hwang, M.D., Ph.D.①②

Edwin G. Wilkins, M.D.②③

Julie C. Lowery, Ph.D.②③

Judy Gentile, R.N. ④

Ann Arbor, Michigan

① Department of Surgery, Hanyang University Hospital

② Section of Plastic Surgery, University of Michigan

③ Center for Practice Management and Outcomes Research,

Ann Arbor VHA Health Services Research and Development Center of
Excellence

④ Department of Nursing, University of Michigan Hospitals

Abstract

Purpose: Among strategies recently proposed to reduce practice variation, promote quality, and control costs in health care delivery, the concept of the clinical pathway has received considerable attention. Because transverse rectus abdominis musculocutaneous (TRAM) breast reconstruction is a common and often costly intervention, we sought to evaluate cost and quality outcomes of a clinical pathways program for this procedure at our institution.

Methods: The TRAM Reconstruction Clinical Pathway (TRCP) was implemented in April, 1996 to standardize postoperative care in this patient population. Outcomes of consecutive pathway cases for the first 14 months of the program were assessed in a retrospective cohort design, using all non-pathway TRAM cases from the 18 months immediately prior to pathway implementation as controls. Outcomes assessed included length of hospital stay (LOS); postoperative complications; total postoperative charges; and total postoperative costs in relative value units (RVUs). Data on these dependent variables were collected from hospital charts and billing records. The effects of pathway implementation on the outcomes of interest were analyzed using ANCOVA (analysis of covariance) in order to control for potential confounding by other independent variables including surgical site (unilateral versus bilateral reconstructions); technique (pedicle versus free TRAMs); timing (immediate versus delayed reconstructions); and pa-

tient age. Finally, a comparison of variances in the outcomes of interest between the two groups was performed using an F test. For all statistical tests, p values of less than or equal to 0.05 were considered significant.

Results: Twenty-nine patients were treated in the TRCP group, while the control population included 40 non-pathway patients. Following implementation of the TRCP, mean LOS decreased from 6.0 to 5.2 days; mean postoperative charges were reduced from \$8587 to \$7744; and mean postoperative costs (in RVUs) declined from 1686 to 1104. ANCOVA showed that the decreases in LOS and RVUs in the TRCP were statistically significant ($p=0.05$ and $p=0.007$, respectively). By contrast, no significant increase in complications was observed following pathway implementation. Variability in the TRCP group, as measured by standard deviation, decreased significantly for both LOS ($p=0.039$) and RVUs ($p=0.023$).

Conclusions: Implementation of the TRCP resulted in significant declines in LOS and total costs. These decreases in resource utilization had no significant effect on postoperative complication rates. While additional research is needed to further assess the impact of clinical pathways, this approach offers considerable promise for improving the cost-effectiveness of health care.

Introduction

In recent years, health care payers and providers have found themselves under increasing pressure to improve quality and contain costs. Purchasers of health care services currently rely on a variety of mechanisms to achieve these goals; prospective payments, pre-authorization for tests and procedures, and utilization review have all been used in attempts to control costs while maintaining or improving quality of care [1]. Responding to these trends, health care providers also have employed various approaches to balance costs and quality, including implementation of practice standards and clinical guidelines.

Among these strategies, the concept of the clinical pathway has received considerable attention. Also known as the "critical pathway", this methodology was originally developed by industrial engineers to define "best" practices and to outline timetables for completion of these tasks [2]. In the 1980s, Zander [3] and Grudich [4] advocated the adaptation and development of clinical pathways for health care as a means of improving patient outcomes while conserving resources. As currently defined, clinical pathways coordinate care for patients undergoing specific treatment interventions through use of a standardized, interdisciplinary process. Steps in this process are sequenced in a predetermined order to produce specific, desired outcomes within a set period of time [5]. By defining "best"

practices and anticipated outcomes, pathways can contribute substantially to continuous quality improvement in patient care.

Clinical pathways have been developed and implemented for a variety of health care interventions, including caesarian section [6], percutaneous transluminal coronary angioplasty [7], burn treatment [8], stroke management [9], and pressure sores [10]. Because implementation of pathways requires commitment of considerable personnel time and institutional resources, pathway development to date has focused primarily on common, high cost interventions. Pathways are not intended to be blindly applied to all patients within a treatment category. Rather, these processes are designed for "average" patients, with the expectation that 20% of patients will vary from the pathway [5].

As described by Gordon [11], several steps are generally followed in the formulation and implementation of clinical pathways: (1) The *focus/recognition phase* sets goals for the proposed protocol and reviews the scientific literature to identify optimal techniques and outcomes. (2) The *assessment and analysis phase* identifies common treatment patterns and devises ways in which to improve practices. (3) In the *development phase*, a multidisciplinary patient care team refines the critical elements needed to achieve the desired outcomes. During this stage, mechanisms are also established to monitor the results of pathway implementation. (4) The final step is the *implementation and evaluation phase* in which the

pathway is initiated. Following implementation, variances and outcomes are studied and appropriate modifications are made in the pathway. As seen in these various phases, clinical pathway development and implementation are ongoing, iterative processes, which continue as long as the pathway remains in use.

Because transverse rectus abdominis musculocutaneous (TRAM) breast reconstruction is a common and often costly treatment intervention, we sought to devise, implement and evaluate a clinical pathways program for this procedure at our institution. Specifically, our goal was to analyze the impact of a TRAM pathway on our resource utilization and quality of care associated with these reconstructions.

Patients and Methods

Pathway Development and Implementation

To devise and initiate the TRAM Reconstruction Clinical Pathway (TRCP), a multidisciplinary team of clinicians was assembled, including a plastic surgeon, clinical nurse specialists, staff nurses, a pharmacologist, and hospital administrators. In an initial step analogous to the Focus/Recognition Phase described by Gordon [11], our team was convened to devise a methodology to reduce practice variation, control costs and maintain (or improve) quality of care

associated with the postoperative management of TRAM reconstruction patients. TRAM flaps were chosen as the focus for this working group due to the high volume and significant expense of these procedures. Because our team initially was relatively unfamiliar with the concept of clinical pathways, we confined our program to postoperative care of this population in an effort to limit the scale of the pilot project. Specifically, the team chose to target length of stay, postoperative costs, and complications as the outcomes to be impacted by the TRCP. Following selection of a clinical focus, outcome data (including complication rates and length of stay) for TRAM flaps performed in the preceding two years were analyzed to identify common practice patterns and to assess the appropriateness of care (Gordon's Assessment/Analysis Phase).

Having defined existing practices, the pathways team proceeded to the Development Phase during which various critical elements of postoperative TRAM patient care were formulated based on current outcomes literature and expert opinions. All aspects of postoperative care were addressed in the TRCP, including fluid and electrolyte management; pain control; pulmonary care; physical activities; diet; pulmonary embolism prophylaxis; antibiotics; catheter care; utilization of blood products; laboratory testing; patient teaching; psychosocial support services; discharge planning; and follow-up care. The TRCP was designed around five components: (1) a coordinated care flow chart displayed at the

nurses' station; (2) preprinted orders; (3) a laminated copy of the pathway illustrated in a flow sheet placed on each patient's chart; (4) a variance tracking tool for review of pathway compliance; and (5) discharge teaching instructions. After review and revision of the various components by team members, the TRCP was finalized. Prior to roll-out of the pathway, clinical nurse specialists on the team conducted training sessions for nursing personnel on use of the pathway. Finally, the TRCP was implemented in April, 1996, and, with minor modifications, has been in continuous use since that time.

Pathway Evaluation

To assess the results of pathway implementation, outcomes of TRAM flap breast reconstructions were reviewed in a retrospective cohort study. All patients treated at our institution under the direction of the TRCP between April 1, 1996, and June 1, 1997, were included in the analysis. Non-pathway TRAM flap patients treated from September 1, 1994, to March 31, 1996, were evaluated as a control group.

The major outcomes of interest included length of hospital stay (LOS), postoperative complications occurring within 30 days of surgery, total postoperative charges and total postoperative costs. Because the TRCP covered only postoperative care, intraoperative charges and costs were not included in our compari-

son. To gain a better understanding of the reasons for any observed changes in length of stay, utilization days for specific resources were also analyzed. Specifically, we examined utilization days for intravenous antibiotics, patient controlled analgesia machines (PCAs), and sequential compression devices (SCDs), because use of these resources was monitored in the clinical pathway. Similarly, individual components of charges and costs were also analyzed, including supplies, pharmaceuticals, and laboratory. Finally, as an indicator of postoperative quality of care, complications diagnosed within 30 days of surgery were assessed for the two study groups. Complications were defined as any medical or surgical problem which arose as a result of the TRAM flap breast reconstruction and which required additional treatment.

Hospital charts were reviewed to obtain data on LOS and complications. Billing data for postoperative care were collected from the medical center finance department. Because the study took place across three fiscal years, all charges were adjusted to 1997 levels. Although this normalization of billing data controlled for inflationary increases over the study period, other secular changes in itemized billings presented additional sources of bias. To gather comparable financial data for the various time periods in the study, a Relative Value Unit (RVU) system was employed. Developed at the University of Michigan by McMahon and coworkers [12], UM RVUs have been assigned to each of the

medical center's fee codes. RVUs are calculated by multiplying the ratio of an individual fee code's charge to a department's total charges by the department's direct costs. Use of the RVU system facilitated comparison of costs across the different fiscal years included in the study.

Chi-square analysis was used to determine if any significant differences existed between the two study groups (TRCP patients and non-pathway controls) on characteristics that might affect outcomes, including: (1) extent of reconstruction (unilateral versus bilateral); (2) type of reconstruction (pedicle versus free TRAM); (3) procedure timing (immediate versus delayed reconstruction) and (4) patient age. To identify changes in the dependent variables of interest, two-sided *t*-tests were used to compare postoperative LOS, charges, and RVUs, while differences in complication rates were analyzed using the chi-square statistic. The clinical variables (including complications) that were found to differ between the two study groups were included in an analysis of covariance (ANCOVA), to control for their effects on length of stay and resource use. Finally, a comparison of the variances of the outcomes of interest between the two groups was analyzed using an *F* test. For all statistical tests, *p* values less than or equal to .05 were considered significant.

Results

The control group included 40 patients who underwent TRAM flap breast reconstruction from September 1, 1994, through March 31, 1996, prior to implementation of the clinical pathway. The experimental group was composed of 29 patients who received TRAM flaps from April, 1996, through June 1, 1997, following implementation of the pathway.

There was no statistically significant difference in average age between the two groups (average age of patients before pathway implementation was 44.7 years, after pathway implementation was 46.8 years). Table 1 shows differences in the distributions of types of procedure between the two groups. While the distribution between immediate and delayed reconstructions was not significantly different, the distributions of free versus pedicle and unilateral versus bilateral were different. A greater percentage of pedicle and unilateral TRAMs occurred in the after pathway group.

Length of stay and days of resource utilization are shown in Figure 1. Mean length of stay decreased significantly from 6.0 days to 5.2 days ($p=0.026$). In addition, mean utilization days of intravenous postoperative antibiotics decreased significantly from 4.3 to 2.4 ($p=0.003$), as did use days of sequential com-

pression devices, from 3.8 to 3.2 days ($p=0.029$). The reduction in utilization days of PCA machines from 3.2 to 2.8 days, however, was not significant.

Nonoperative-hospital charges and RVUs are shown in Figures 2 and 3. All charges, including total charges, decreased after implementation of the pathway. However, the only significant reduction occurred with mean total laboratory charges, from \$738 to \$519. Non-operative RVUs also decreased after pathway implementation, with a statistically significant reduction in all categories, with the exception of laboratory services. Mean total RVUs decreased 35 percent from 1686 to 1104. Rates of early complications between the two groups were virtually identical at 0.28 (see Table 2).

Given the clinical differences between the two groups (i.e., differences in distribution of free versus pedicle and unilateral versus bilateral procedures) and the possibility that these differences might affect the outcomes of interest, it is important to control for these potential confounders in analyzing the effects of the TRCP on the outcomes of interest. Therefore, ANCOVA (analysis of covariance) was used to determine if the effects of pathway implementation were significant after controlling for these confounding clinical variables. Patient age and timing of reconstruction (immediate versus delayed) were also included as independent variables in the ANCOVA, even though there were no observed differences in these variables between the two groups, to determine whether these variables had

an effect on LOS or resource use, regardless of pathway implementation. Complications were also included as independent variables in this analysis for similar reasons. Length of stay, nonoperative-hospital charges, and nonoperative-RVUs were included as dependent variables.

Table 3 provides results of the ANCOVA. Controlling for the patients' clinical characteristics, implementation of the TRAM pathway had a significant effect on both length of stay and non-operative RVUs, but not on non-operative charges. The direction of the effect of the pathway was negative, as hypothesized—i.e., patients treated after implementation of the pathway had a decreased LOS and reduced resource utilization, as measured by RVUs. The only clinical characteristic that had a significant effect on the outcomes was the presence of early complications, which was significant for all three outcome measures. As expected, the effect of this variable was positive—i.e., complications were associated with longer LOS and higher resource utilization.

Results of the analysis of differences in the variability of resource utilization are shown in Table 4. Variability, as measured by variance, decreased after pathway implementation for all of the resources measured. This difference was significant for all resources except pharmacy charges, pharmacy RVUs and total charges.

Discussion

In this study we implemented a clinical pathway in an effort to improve efficiency and reduce variation in the postoperative care of patients undergoing TRAM reconstruction. We found that implementation of the pathway had significant effects on both length of stay and non-OR RVUs, even after controlling for the effects of other clinical variables, including complications, age, extent of reconstruction (unilateral or bilateral), timing of reconstruction (immediate versus delayed), and type of procedure (pedicle versus free flaps). Pathway implementation realized these savings without increasing complication rates during the postoperative period. Although the etiologies for the observed decreases in LOS and postoperative RVU utilization are not uniformly apparent from these results, the data contain some clues as to the mechanisms by which greater efficiency was achieved. As noted above, pathway implementation resulted in significant decreases in practice variation for utilization of a variety of resources including SCDs, PCAs, intravenous antibiotics, and laboratory tests. Furthermore, overall use of SCDs and postoperative antibiotics also declined in the pathway group. By standardizing indications and protocols for these interventions, the pathway may have controlled overuse of such resources. Also, the pathway may have also reduced resource utilization through a heavy emphasis on early postoperative mobi-

lization. Pathway patients were encouraged to ambulate early and often following their surgeries, likely resulting in decreased use of interventions such as SCDs and in shortened lengths of stay.

Major components of both charges and RVUs included the use of supplies, medications, and laboratory tests. Both supply and pharmacy RVUs decreased significantly after pathway implementation, while supply and pharmacy *charges* did not decrease significantly. This suggests that the unit price for supply and pharmacy items increased over and beyond inflation, while the quantity of these items required for TRAM patients decreased after pathway implementation. The results also emphasize the importance of adjusting for inflation or price changes when comparing resource utilization across time periods or across institutions (hence the use of RVUs). It is interesting to note that laboratory RVUs did not decrease significantly, but their associated charges did. This latter observation may reflect a secular trend within our medical center, with charges for some goods and services actually decreasing during the study period.

With the expanding use of clinical pathways, these protocols appear to offer a variety of potential advantages. As demonstrated in our study and elsewhere(3)(4)(10), pathways may help conserve increasingly scarce health care resources. Furthermore, by reducing treatment variation, pathways may also achieve another important goal. As we seek to find ways of reducing overutiliza-

tion of health care resources, it is important that we not err on the side of promoting underutilization of resources, which can compromise the quality of patient care. Thus, the purpose of implementing clinical pathways is not solely to reduce resource utilization, but also to reduce variability. In this way we not only discourage the excessive use of resources but also reduce the probability of providing inadequate care. While resource utilization decreased significantly after pathway implementation, the incidence of early complications did not change, suggesting that quality was not compromised with use of the pathway.

In addition to controlling costs, clinical pathways also provide a useful framework for implementation of continual quality improvement (CQI) programs in health care. Through standardization of treatment interventions, pathways can facilitate dissemination of innovations as well as supply a mechanism for tracking outcomes. Because the clinical pathway is an iterative process, this approach is designed to continuously evaluate and refine existing practices.

Finally, dissemination of clinical pathways also may offer medicolegal benefits. A recent review suggests that implementation of pathways and the documentation associated with these protocols may help avert malpractice claims by corroborating the thoroughness of care[13].

Our study had some limitations. A randomized controlled design could not be used due to practical considerations (mainly limitations in staffing re-

sources). As a result, the differences observed could be attributed to other, hospital-wide cost-saving measures (i.e., secular trends). However, secular trends appear unlikely as etiologies for these observations, because the outcomes exhibiting the greatest changes over time were the same parameters specifically targeted by the pathway. Another potential weakness in the study was our focus on postoperative care. Had the pathway included preoperative and intraoperative interventions in addition to postoperative patient management, the impact of this approach might have been even more remarkable. Finally, our only outcome measure reflecting quality of care was postoperative complication rates. In future studies, the authors would advocate using more comprehensive assessments including patient satisfaction, hospital readmission rates, health status and quality of life.

Because implementation of a clinical pathway for TRAM breast reconstruction achieved our objectives of reducing resource use without increasing complication rates, this experience has served as a model for development and implementation of additional pathways for plastic surgery procedures in our hospital. At the present time, we are continuing to monitor and modify the TRAM pathway at regular intervals. Efforts are currently underway to revise and expand the TRCP to encompass preoperative, intraoperative, and postoperative care. Ad-

ditional clinical pathways are being implemented for patients undergoing pressure sore repairs and free tissue transfers.

Address correspondence to: Edwin G. Wilkins, M.D.

University of Michigan Medical Center, Section of Plastic Surgery

2130 Taubman Center, 1500 East Medical Center Drive

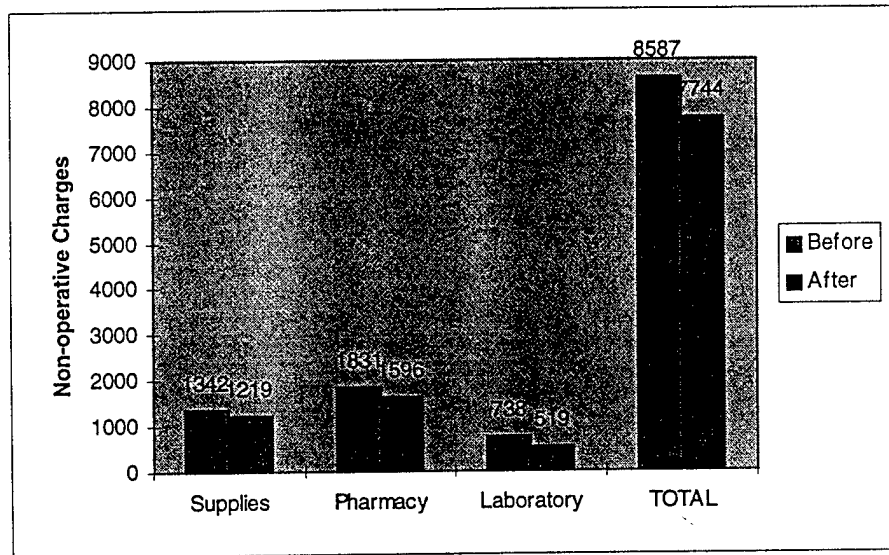
Ann Arbor, MI 48109-0340

Telephone: 313-936-5885

Supported by U.S. Army Medical Research and Development Command Grant

AIBS #1487

Figure 2 Non-operative Charges



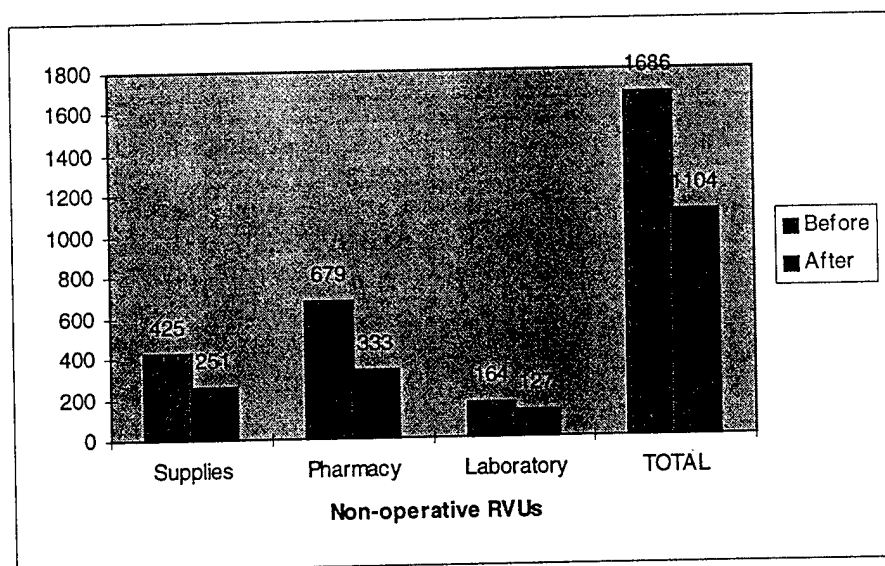
Supplies: p -value=0.332

Pharmacy: p -value=0.314

Laboratory: p -value=0.018

TOTAL charges: p -value=0.196

Figure 3 Non-operative RVUs



Supplies: p -value=0.047

Pharmacy: p -value=0.0002

Laboratory: p -value=0.116

TOTAL charges: p -value=0.0004

Table 1 Clinical Summary of TRAM procedures

TRAM Type	Before Pathway N=40		After Pathway N=29		p-value*
	Number	%	Number	%	
Immediate	22	55.0	19	65.5	0.17
Delayed	18	45.0	10	34.5	
Free	22	55.0	7	24.1	0.01
Pedicle	18	45.0	22	75.9	
Unilateral	24	60.0	25	86.2	0.02
Bilateral	16	40.0	4	13.8	

*For chi-square statistic.

Table 2 Complications during hospital stay

Complication type	Before Pathway		After Pathway	
	Number	%	Number	%
Infection	1	2.5	0	0
Hematoma or seroma	0	0	0	0
Partial flap loss	3	7.5	1	3.4
Mastectomy skin flap loss	0	0	0	0
Pul. embolism or DVT	0	0	0	0
Atelectasis or effusion requiring prolonged stay	1	2.5	1	3.4
UTI	1	2.5	3	10.3
Venous congestion of flap requiring leech therapy	2	5.0	1	3.4
Antibiotics-related colitis	2	5.0	0	0
Prolonged N/V	1	2.5	1	3.4
Vas. compromise of flap requiring re-exploration	0	0	1	3.4
Total (p-value = 0.99)	11	27.5	8	27.6

Table 3 Results of ANCOVA

<i>Independent Variables</i>	<i>p-value (direction of effect*)</i>		
	<i>Dependent Variables**</i>		
	Length of Stay	Non-OR Charges	Non-OR RVUs
TRAM Pathway	0.051 (-)	0.587 (-)	0.007 (-)
Early Cx	0.001 (+)	< 0.001 (+)	0.002 (+)
Age	0.101 (+)	0.537 (+)	0.199 (-)
Unilateral	0.604 (-)	0.332 (-)	0.184 (-)
Immediate	0.892 (+)	0.878 (+)	0.743 (-)
Free	0.775 (-)	0.164 (+)	0.155 (+)

* A (+) effect indicates that an increase in the independent variable is associated with an increase in the dependent variable. A (-) effect indicates that an increase in the independent variable is associated with a decrease in the dependent variable.

** A separate ANCOVA analysis was performed for each dependent variable; each analysis included all of the independent variables.

Table 4 Comparison of Variances of Resource Utilization

	Variance*		p-value**
	Before	After	
Days of resource utilization			
Length of stay	2.66	1.39	0.039
Days of IV ABX ¹	6.35	2.40	0.004
Days of PCA ²	1.37	0.58	0.010
Days of SCD ³	2.43	0.94	0.005
Non-operative hospital charges			
Total	8,579,990	4,830,087	0.058
Supplies	416,025	157,609	0.004
Pharmacy	935,089	850,084	0.401
Laboratory	198,916	93,636	0.020
Non-operative RVUs			
Total	594,690	286,482	0.023
Supplies	255,025	26,569	< 0.001
Pharmacy	148,996	115,600	0.244
Laboratory	14,161	5,476	0.005

*Variance = (Std Dev)².

**For F-statistic.

¹Days of postoperative IV antibiotics³Days of SCDs²Days of PCA

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**Michigan Breast Reconstruction Outcome Study,
DAMD 17-94-4044**

**Annual Report
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ATTACHMENT FOUR

Manuscript: "Determinants of Patient Satisfaction in Post-Mastectomy Breast Reconstruction". Submitted to *Plastic and Reconstructive Surgery*.

**Determinants of Patient Satisfaction
in Post-Mastectomy Breast Reconstruction**

Amy K. Alderman, M.D.¹

Edwin G. Wilkins, M.D., M.S.^{1,2}

Julie C. Lowery, Ph.D.²

Myra Kim, Ph.D.²

Jennifer A. Davis, M.H.S.A.²

Ann Arbor, Michigan

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Abstract

¹ University of Michigan Section of Plastic Surgery

² VA Center for Practice Management and Outcomes Research, Ann Arbor, Michigan

In today's increasingly competitive health care marketplace, consumer satisfaction has become an important measure of quality. Furthermore, measures of satisfaction with treatment interventions are influential factors in determining patients' and payers' choices of health care. This study sought to evaluate satisfaction with post-mastectomy breast reconstruction and to assess the effects of procedure type and timing on patient satisfaction.

As part of the Michigan Breast Reconstruction Outcome Study (MBROS), patients undergoing first-time mastectomy reconstruction were prospectively evaluated, including cohorts of women choosing expander/implant, pedicle TRAM flap, and free TRAM flap procedures. Preoperatively and one year postoperatively, participants completed a questionnaire which collected a variety of health status information. The postoperative questionnaire had an additional seven items assessing both general satisfaction with reconstruction (five items) and aesthetic satisfaction (two items) as separate subscales. Patients were asked to respond to each item using a five point Likert scale. Item responses ranged from 1, indicating high satisfaction, to 5, reflecting low satisfaction. In the data analysis, only patients responding with a 1 or 2 for all of the items within a subscale were classified as "satisfied" for the subscale. To assess the effects of procedure type (implant, pedicle TRAM flap, and free TRAM flap) and timing (immediate versus delayed) on satisfaction and to control for possible confounding effects from other independent variables, multiple logistic regression was employed. In our analysis, odds ratios and associated 95% confidence intervals were calculated for each independent variable in the regression. Furthermore, statistical significance was designated at the $p \leq 0.05$ level.

A total of 212 patients were followed during the period of 1994 to 1997, including 141 immediate and 71 delayed reconstructions. The study population consisted of 49 expander/

implant, 102 pedicle TRAM flap, and 61 free TRAM flap reconstruction patients. The analysis showed a significant correlation between procedure type and patient satisfaction. TRAM flap patients (both free and pedicle) appeared to have significantly greater general and aesthetic satisfaction compared to expander/implant patients ($p = 0.03$ and 0.001 , respectively). Furthermore, pedicle TRAM flap patients were more aesthetically satisfied than those with free TRAM flaps ($p = 0.072$). The other independent variables of age and procedure timing did not appear to significantly affect either general or aesthetic satisfaction. However, preoperative physical activity was positively correlated with general satisfaction at the $p = 0.034$.

The choice of procedure appears to have a significant effect on both aesthetic and general patient satisfaction with breast reconstruction. In this study, autogenous tissue reconstructions produced higher levels of patient aesthetic and general satisfaction compared with implant techniques. Pedicle and free TRAM flap patients do not appear to differ significantly in general satisfaction. However, women receiving pedicle TRAM flaps reported greater aesthetic satisfaction compared with patients undergoing free TRAM flaps. Furthermore, patient age and procedure timing may not have an effect on patient satisfaction with breast reconstruction.

In today's increasingly competitive health care marketplace, the issue of measuring quality of care has become the topic of considerable interest and controversy among payers, providers, and consumers. Although little consensus on methodology exists for assessing quality, an increasing number of health services researchers, managed care providers, and patients are relying on patient satisfaction data to provide insights into the appropriateness and effectiveness of medical interventions. Many physicians continue to mistrust patient satisfaction surveys, believing them to be poor indicators of quality. However, consumer evaluations of health care have gained widespread recognition in both the public and private sectors as valid quality indicators¹. As Donabedian argued over thirty years ago, the ultimate validator for quality of care is its effectiveness in achieving or producing health and satisfaction². Vuori sums up the case for patient satisfaction assessments when he asserts, "Put simply, care cannot be of high quality unless the patient is satisfied."¹

As valid quality measures, patient satisfaction data are being used within the health care industry for a variety of purposes. Most notably, this information commonly serves as a basis for policy decisions by payers and managed care providers.³ Results of satisfaction surveys not only help determine which treatment interventions will be financially supported but also decide where (and by whom) these services will be rendered. Satisfaction data also are playing increasingly important roles in quality improvement programs within health care systems. Patients' views on the structure, process, and outcomes of care supply feedback to guide providers and administrators in redesigning health care delivery. Finally, the results of satisfaction surveys may also assist patients choosing among alternative medical interventions. As consumers become more actively involved in directing their own health care, knowledge of previous patients' experiences can help direct consumers' treatment decisions.²⁷ This increasing reliance on patient

satisfaction surveys in policy formulation, quality improvement, and treatment decision-making has compelled clinicians and researchers to evaluate health care not just in terms of objective outcomes (complication rates and length of hospitalization, for example) but also from the consumer's point of view.

In spite of the growing importance of consumer satisfaction data, there remains a relative paucity of published research on these outcomes within the plastic surgery literature, particularly in the area of post-mastectomy breast reconstruction. Although a small number of previous studies have gathered data on patients' satisfaction with reconstruction, research in this area remains limited to studies of single procedure types and small populations of patients.⁴⁻⁶ Furthermore, rarely controlled for are the possible confounding factors such as the patient's age and the timing of the reconstruction.⁶⁻⁷ To address these limitations in previous studies, we sought to evaluate the effects of reconstructive technique, procedure timing, and patient age on aesthetic and general satisfaction in women undergoing breast reconstruction.

Methods

Study Population

Patients were recruited as part of the Michigan Breast Reconstruction Outcome Study (MBROS), a prospective cohort study of mastectomy reconstruction patients. Women undergoing first-time immediate or delayed reconstructions with expander/implant, pedicle TRAM flap, and free TRAM flap techniques were eligible for participation. Both unilateral and bilateral procedures were included. Twenty-three plastic surgeons from twelve centers in Michigan, Pennsylvania, Louisiana, and Ontario contributed patients from 1994 to 1998. Patients enrolled in the study from 1994 to 1997 were included in the analysis. Post-operative data are not yet available on 1998 patients.

Data Collection

After giving informed consent, participants completed a preoperative battery of questionnaires including surveys of demographic information as well as items assessing general health status, psychosocial status, and physical functioning. One year following completion of reconstruction, patients were given a postoperative questionnaire evaluating the same parameters along with seven other questions measuring satisfaction with reconstruction. Factor analysis separated the seven items into two subscales, five questions assessing general satisfaction and two measuring aesthetic satisfaction (Figure 1). Item responses were scored using a five point Likert scale ranging from very satisfied to very dissatisfied.

Responses for each of the subscales were dichotomized into “satisfied” versus “not satisfied” using the following criteria: (1) scores of “very satisfied” or “satisfied” (a “4” or “5” on the 5 point Likert scale) for all questions within a subscale were considered to be “satisfied;” (2) all other scores were considered to be “not satisfied.” This stringent criterion was used for dichotomizing the data because, in general, previous research has found that the majority of patients are satisfied with their breast reconstruction.⁸ Therefore, this dichotomization allows for the identification of factors associated with very high levels of satisfaction.

Analysis

To compare the proportion of satisfied patients (both generally and aesthetically) among the three procedure types (expander/implant, pedicle TRAM flap, and free TRAM flap) and between the two timing groups (immediate and delayed), multiple logistic regression was used. The regression also adjusted for possible confounding effects from other independent variables. Specifically, patient age and preoperative physical activity level were included as potential

confounding variables. Our hypothesis was that older, less physically active patients would be less satisfied with the reconstruction. Age was coded as follows: 1 = <39 years, 2 = 40-49 years, 3 = 50-59 years, and 4 = ≥ 60 years. Physical activity was coded as follows: 1 = no exercise; 2 = regular mild exercise, or moderate exercise 1-2 times/week; 3 = moderate exercise ≥ 3 times/week, or regular vigorous exercise.²

For each subscale (general satisfaction and aesthetic satisfaction), two separate multiple logistic analyses were performed. The first analysis assessed the difference in satisfaction between autogenous reconstructions (free and pedicle TRAM flaps) and expander/implant reconstructions. The second analysis evaluated the difference in satisfaction among patients with free and pedicle TRAM flaps. For each analysis, the aforementioned potential confounding variables along with procedure timing were included.

The odds ratio (OR) and its 95% confidence interval were calculated for each of the independent variables included in the multiple logistic regression analyses. For categorical variables, the OR measures the odds of being satisfied for the indicated category relative to the reference category. For continuous variables, the OR measures the relative change in odds of being satisfied for a one unit increase in the continuous variable. Statistical significance was set at the $p \leq .05$ level.

Results

By April 15, 1998, 212 women had completed their one-year postoperative questionnaires. Distribution of cases by reconstruction type and timing are summarized in Table

² Examples of mild exercise are leisurely walking, gardening, leisurely biking. Examples of moderate exercise are 30 minutes or less of low-impact aerobics, jogging, tennis, biking, swimming. Examples of vigorous exercise are 30 minutes or more of aerobics, running, basketball, stair-stepping.

1. Of the three types of procedures, pedicle TRAM flap reconstructions were the largest cohort. Approximately twice as many immediate reconstructions were performed as compared with delayed procedures. Patients with expander/implant procedures had a much larger percentage of immediate reconstructions (84%) compared to patients with pedicle and free TRAM flap reconstructions (60% and 64%, respectively). No significant differences were observed across procedure types in the following patient demographics: marital status, education, race, income, employment status, and payer. Ages of the patients in the different procedure groups were also not significantly different, but were nearly so ($p = .09$), with pedicle TRAM flap patients being the oldest (mean = 49.4 years) followed by implant patients (mean = 48.5 years) and free TRAM flap patients (mean = 46.4 years).

General Satisfaction

The results of the multiple logistic regression for general satisfaction are shown in Tables 2 and 3. In our initial analysis, we compared satisfaction of patients who had undergone TRAM flaps (free and pedicle combined) to those undergoing expander/implant reconstruction (Table 2). The analysis revealed that TRAM flap patients (both pedicle and free) were more generally satisfied than expander/implant patients ($p = 0.03$). The odds ratio of 2.17 indicates that TRAM flap patients are more than twice as likely to be satisfied compared to expander/implant patients. The regression showed no significant effect of procedure timing or age on general satisfaction, although older women tended to be less satisfied. In addition, the OR for preoperative physical activity was estimated to be 1.68 ($p = 0.03$). Women who exercised at the mild to moderate level or at the moderate to vigorous level were 1.68 times more likely to be generally satisfied than women who did not exercise or who exercised at the mild to moderate level.

When the same analysis was repeated to compare general satisfaction outcomes between pedicle and free TRAM flap patients (Table 3), no significant differences between procedure types were observed. All other ORs (for timing, age, and preoperative physical activity level) remained similar to the previous analysis.

Aesthetic Satisfaction

Multiple logistic regression was carried out to assess the effects of reconstruction type (expander/implant versus TRAM flap reconstructions), procedure timing, patient age, and preoperative activity level on aesthetic satisfaction (Table 4). Women receiving TRAM flaps were significantly more aesthetically satisfied than expander/implant patients. Specifically, TRAM patients were estimated to be 4.72 times ($p < 0.001$) more likely to be satisfied than expander/implant patients. The other independent variables included in our analysis (timing of reconstruction, patient age, and preoperative activity) did not have significant effects.

As with our analysis for general satisfaction described above, we repeated the analysis to compare pedicle and free TRAM flap patients for differences in aesthetic satisfaction (Table 5). While no significant effects were noted for procedure timing, patient age, or preoperative activity level, free TRAM flap patients were found to be less aesthetically satisfied than women receiving pedicle TRAM flaps (marginally significant at $p = 0.07$). The odds ratio of 0.504 for free TRAM patients indicates that these patients were half as likely to be aesthetically satisfied compared to pedicle TRAM patients.

Discussion

Among researchers and clinicians, views on the significance of patient satisfaction have evolved considerably over the last 40 years. In the 1950's, patient satisfaction was initially studied as a determinant of patient compliance. During this early period, research on health care

satisfaction was conducted primarily by sociologists who noted a link between patient satisfaction and compliance, sparking interest among providers seeking to improve clinical outcomes.¹ The 1960's and 1970's witnessed the rise of consumerism in the United States. Health care came to be viewed as a commodity to be purchased and sold like most other consumer products. In the 1980's, this "health care commodity" philosophy provided consumers, providers, and payers with two agendas for evaluating patient satisfaction: (1) health care accountability -- a product of the earlier consumerism movement, and (2) health care efficiency, an increasingly important factor in the service industry.¹ Today, as the health care marketplace becomes increasingly competitive, consumer satisfaction is considered an important measure of health care quality and, as such, often plays a key role in determining patients' and payers' choices of services and providers. Patient satisfaction has evolved from a means of improving patient compliance into a highly valued outcome of care.¹

Despite growing interest in assessing health care satisfaction, the existing breast reconstruction literature contains relatively few studies evaluating these outcomes. Although some investigators describe patient satisfaction measurements, many reports have been hampered by methodological flaws including poorly defined patient populations and outcomes.¹ Furthermore, previous studies often have not compared satisfaction outcomes by procedure type or timing of reconstruction.^{4-6,9} Given the health care industry's current focus on consumer satisfaction and the relative lack of plastic surgery research in this area, the importance of administering a patient satisfaction assessment in the MBROS questionnaire became readily apparent early in the design of our study.

In addition to the rationale outlined above, we elected to include a patient satisfaction instrument in our outcome study for another reason: the deficiency of a standardized evaluation

of aesthetic results in breast reconstruction. Previously published rating scales for assessing aesthetic results have demonstrated poor inter-rater and intra-rater reliability when used by panels of physicians.¹⁰ Additional attempts by our group to improve this reliability have been largely unsuccessful. As a consequence, we have come to rely on patients' subjective assessments as one of our primary tools for comparing aesthetics across procedures. In doing so, we must bear in mind that patients' evaluations of aesthetic outcomes may differ from those of providers.¹¹ For example, reconstructive surgeons have suggested that free TRAM flap reconstructions, compared to pedicle TRAM flaps, offer superior aesthetic results due to improved medial breast mound contour and greater flexibility for flap inseting.¹² However, our preliminary data indicate that patients may be more aesthetically satisfied with pedicle TRAM flap reconstructions. This illustrates that an operation surgeons classify as superior technically does not always provide greater consumer satisfaction.

Our study results indicate that patients do concur with the growing consensus in the plastic surgery literature that autogenous tissue reconstructions offer superior results compared to implant techniques.¹³⁻¹⁶ TRAM flap reconstructed patients were significantly more satisfied than women choosing implant procedures. These differences were noted for both general and aesthetic satisfaction. A variety of possible explanations exist. The questionnaire's aesthetic subscale addressed issues of breast contour and softness, suggesting that autogenous reconstructions provide a result more consistent with the patient's original breast tissue. Furthermore, survey items addressing general satisfaction reflected patients' perception of the treatment process; that is, information gathering, decision making, and undergoing surgery. Perhaps patients feel less informed about the implants, especially with the public's recent concern regarding the unproven association between autoimmune disorders and breast implants. Controversial information can

increase the complexity of the decision making process, potentially creating less satisfied consumers.

In addition to the important differences discovered in satisfaction among the types of reconstruction, an equally important finding is the absence of a significant procedure time effect on satisfaction. In recent years, views on the appropriate timing for breast reconstruction have undergone considerable evolution. Prior to 1990, it was commonly suggested that women undergoing mastectomy must grieve the loss of their breast before they can obtain psychosocial equilibrium.¹⁸ Furthermore, some authors maintained that patients forced to live with mastectomy scars prior to receiving reconstruction would ultimately be more satisfied with the results of their reconstructions.²⁶ More recently, however, the plastic surgery literature has shifted in favor of immediate reconstruction. Several investigators have demonstrated the safety as well as the psychosocial benefits of immediate reconstruction.²⁰⁻²³ Other authors have questioned the need for a mastectomy patient to live with her deformity in order to make her fully appreciate her eventual reconstruction.²⁴ Our study results support this more recent and positive view of immediate reconstruction. We did not observe significant differences in either general or aesthetic satisfaction between patients undergoing delayed and immediate reconstruction. Based on these data, denying women the option of immediate reconstruction in the hopes of producing greater patient satisfaction does not appear to be justified.

Our observations of the association between preoperative physical activity levels and patient satisfaction raise some intriguing questions. We found that women reporting higher levels of activity were more generally satisfied than patients with less active lifestyles. However, activity levels did not appear to have a significant effect on aesthetic satisfaction. Several plausible explanations exist for the association between baseline physical activity level and

general satisfaction. Because physically active patients tend to enjoy superior health status, these dividends may translate into fewer surgical complications, improved clinical outcomes, and therefore greater satisfaction with the reconstruction. Alternatively, a previous study by Segars demonstrated that increased physical activity levels were associated with improvements in psychosocial well-being among breast cancer patients.²⁵ Greater general satisfaction noted in our active patient population may reflect higher levels of psychosocial well-being. Psychologically and socially well-adjusted patients may view their reconstructions more favorably.

The major limitation of this study is the possibility of confounding inherent in the use of a prospective cohort design rather than a randomized controlled trial. For ethical and practical reasons, we were unable to randomize patients by procedure type and reconstructive timing. Understandably, most patients want the freedom to choose their mode of surgery. However, the various treatment groups have proven to be very similar in their demographic characteristics. Furthermore, we have controlled for those variables in which there was a significant, or nearly significant, difference across the groups. Although we controlled for several independent variables in our regression, there may be other unsuspected independent variables which impact patient satisfaction.

Conclusions

General Satisfaction

In our analysis of MBROS patients, women choosing TRAM flap reconstructions were significantly more generally satisfied with their reconstruction compared to patients with expander/ implant reconstructions. However, no significant difference was noted in general satisfaction between women receiving free and pedicle TRAM flap reconstructions. Satisfaction also appeared linked to physical activity; more active women expressed greater general

satisfaction with reconstruction. Finally, procedure timing and patient age had no significant effects on this outcome.

Aesthetic Satisfaction

Procedure choice had a significant effect on aesthetic satisfaction: TRAM flap patients were significantly more satisfied than women undergoing expander/ implant reconstruction. Furthermore, patients receiving pedicle TRAM flap reconstructions were more aesthetically satisfied than those choosing free TRAM flaps. Preoperative physical activity level, patient age, and timing of procedure did not have significant effects on aesthetic satisfaction.

Table 1: Study Population

	Expander/Implant		Pedicle TRAM		Free TRAM		TOTAL
	N	%*	N	%*	N	%*	
Immediate	41	83.7	61	59.8	39	63.9	141
Delayed	8	16.3	41	40.2	22	36.1	71
TOTAL	49	100.0	102	100.0	61	100	212

*Percentage of total represented by immediate and delayed procedures.

Figure 1: Satisfaction Questions

Subscale: General Satisfaction

1. Knowing what I know today, I would definitely choose to have breast reconstruction.
2. Knowing what I know today, I would definitely choose to have the type of reconstruction I had.
3. Overall, I am satisfied with my reconstruction.
4. I would recommend the type of reconstructive procedure that I had to a friend.
5. I felt that I received sufficient information about my reconstruction options to make an informed choice of either the TRAM or Implant procedure.

Subscale: Aesthetic Satisfaction

1. The size and shape of my breasts are the same.
2. My reconstructed breast(s) feel soft to the touch.

Table 2:
Multiple Logistic Regression of General Satisfaction
by Procedure Type: TRAM vs. Expander/Implant

Independent Variable	Odds Ratio (95% Confidence Interval)	p-value
Procedure type: TRAM vs. Implant	2.167 (1.063, 4.416)	0.033
Timing: Delayed vs. Immediate	0.983 (0.491, 1.969)	0.962
Age ¹	0.860 (0.598, 1.238)	0.418
Pre-operative physical activity ²	1.684 (1.040, 2.725)	0.034

¹1=<39 years, 2=40-49 years, 3=50-59 years, 4=≥60 years.

²1=no exercise, 2=mild to moderate exercise, 3=moderate to vigorous exercise.

Table 3:
Multiple Logistic Regression of General Satisfaction
by Procedure Type: Free vs. Pedicle TRAM

Independent Variable	Odds Ratio (95% Confidence Interval)	p-value
Procedure type: Free vs. Pedicle TRAM	1.195 (0.530, 2.698)	0.668
Timing: Delayed vs. Immediate	1.141 (0.521, 2.498)	0.742
Age ¹	0.795 (0.511, 1.237)	0.310
Pre-operative physical activity ²	1.742 (0.982, 3.090)	0.058

¹1=<39 years, 2=40-49 years, 3=50-59 years, 4=≥60 years

²1=no exercise, 2=mild to moderate exercise, 3=moderate to vigorous exercise

Table 4:
Multiple Logistic Regression of Aesthetic Satisfaction
by Procedure Type: TRAM vs. Expander/Implant

Independent Variable	Odds Ratio (95% Confidence Interval)	p-value
Procedure type: TRAM vs. Implant	4.721 (2.326, 9.585)	0.001
Timing: Delayed vs. Immediate	0.734 (0.379, 1.423)	0.360
Age ¹	0.880 (0.617, 1.255)	0.481
Pre-operative physical activity ²	1.083 (0.681, 1.723)	0.737

¹1=<39 years, 2=40-49 years, 3=50-59 years, 4=≥60 years.

²1=no exercise, 2=mild to moderate exercise, 3=moderate to vigorous exercise.

Table 5:
Multiple Logistic Regression of Aesthetic Satisfaction
by Procedure Type: Free vs. Pedicle TRAM

Independent Variable	Odds Ratio (95% Confidence Interval)	p-value
Procedure type: Free vs. Pedicle TRAM	0.504 (0.239, 1.063)	0.072
Timing: Delayed vs. Immediate	0.907 (0.433, 1.903)	0.797
Age ¹	0.943 (0.613, 1.450)	0.789
Pre-operative physical activity ²	0.941 (0.542, 1.634)	0.829

¹1=<39 years, 2=40-49 years, 3=50-59 years, 4=≥60 years.

²1=no exercise, 2=mild to moderate exercise, 3=moderate to vigorous exercise.

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Corresponding author:

Amy Alderman, M.D.

University of Michigan, Section of Plastic Surgery
2130 Taubman Center
1500 E. Medical Center Drive
Ann Arbor, MI 48109-0340

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**Michigan Breast Reconstruction Outcome Study,
DAMD 17-94-4044**

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ATTACHMENT FIVE

Abstract: “Quality of Life and Affective Distress in Women Seeking Reconstruction for Breast Cancer”. Presented at The Society of Behavioral Medicine, Twentieth Annual Scientific Session, San Diego, CA, March 3-6, 1999.

ABSTRACT TYPING FORM

QUALITY OF LIFE AND AFFECTIVE DISTRESS IN WOMEN SEEKING - RECONSTRUCTION FOR BREAST CANCER

Randy S. Roth, Ph.D., Edwin G. Wilkins, M.D., University of Michigan
Medical Center, Julie C. Lowery, Ph.D., Jennifer Davis, B.A., Ann
Arbor Veterans Affairs Medical Center

This study examined the psychosocial and functional status of women (N=235) seeking breast reconstruction following a diagnosis of breast cancer. Subjects were participants in the Michigan Breast Reconstruction Outcomes Study, a prospective multicenter study comparing longterm outcomes for autologous tissue vs. implant post-mastectomy breast reconstruction. For this analysis pre-surgical measures of quality of life and psychological functioning were compared for women (N=151) who underwent breast reconstruction at the time of their mastectomy (Immediate) with those (N=84) seeking reconstruction following prior mastectomy (Delayed). All subjects completed a pre-surgical battery of psychometric inventories assessing sociodemographic variables, including the MOS SF-36 and FACT-B, two measures of quality of life, and the Brief Symptom Inventory which measures various dimensions of affective distress. Chi-square and ANOVA analyses were employed to compare the Immediate vs. Delayed cohorts.

The results revealed general impairment of psychosocial functioning and quality of life for the Immediate group. On the MOS SF-36 Immediate patients reported greater disturbance in work and daily activities due to emotional problems ($p<.0001$), more frequent interference in social activities due to physical or emotional problems ($p<.01$), less vitality ($p<.05$), and reduced overall health status ($p<.01$). On the FACT-B, the Immediate group reported greater impairment in general health status ($p<.05$), emotional well-being ($p<.0001$), and functional status ($p<.05$). The Immediate group also complained of more severe symptoms of anxiety ($p<.0001$), depression ($p<.05$), obsessive-compulsive traits ($p<.01$), and general affective distress ($p<.05$). No group differences were obtained for age, marital status, ethnic group, somatization, bodily pain, perceived general health and somatic complaints. These results reflect a relatively high incidence of psychosocial and functional distress among women recently diagnosed with breast cancer and awaiting surgical intervention.

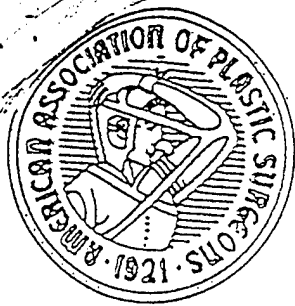
CORRESPONDING AUTHOR: Randy S. Roth, Ph.D., Dept. of Physical
Medicine and Rehabilitation, University of Michigan Medical Center, Ann
Arbor, Michigan, 48109, U.S.A.

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ATTACHMENT SIX

Abstract: “Determinants of Patient Satisfaction in Post-Mastectomy Breast Reconstruction”, American Association of Plastic Surgeons, 78th Annual Meeting, Colorado Springs, Colorado, May 1-5, 1999.



AMERICAN ASSOCIATION OF PLASTIC SURGEONS ABSTRACT FORMAT - 1999 ANNUAL MEETING

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Court B. Cutting, M.D.
IRPS - NYU Medical Center
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ABSTRACT TEXT

Title

DETERMINANTS OF PATIENT SATISFACTION IN POST-MASTECTOMY BREAST RECONSTRUCTION

Text

Introduction: In today's increasingly competitive medical marketplace, patients and payers are becoming increasingly reliant on consumer satisfaction data as quality of care indicators and as a basis for health care decision-making. This study sought to evaluate patient satisfaction with post mastectomy breast reconstruction and to assess the effects of procedure type and timing on satisfaction.

Methods: As part of the Michigan Breast Reconstruction Outcome Study (MBROS), patients undergoing first-time mastectomy reconstruction were prospectively evaluated, including cohorts of women choosing expander/implant, pedicle TRAM and free TRAM procedures. One year postoperatively, patients were administered a survey which included seven items assessing both general satisfaction with reconstruction (five items) and aesthetic satisfaction (two items) as separate subscales. Patients were asked to respond to each item using a five point Likert scale. Item responses ranged from 1, indicating high satisfaction, to 5, reflecting low satisfaction. In the data analysis, only patients responding with a 1 or 2 for all of the items within a subscale were classified as "satisfied" for the subscale. To assess the effects of multiple independent variables (procedure type, timing of reconstruction, patient age and preoperative physical activity level) on the dependent variables of interest (general and aesthetic satisfaction) multiple logistic regression was used. In our analysis, statistical significance was defined as $p \leq 0.05$.

Results: A total of 212 patients were evaluated during the period 1994 to 1997, including 141 immediate and 71 delayed reconstructions. Among the study population, 49 received expander/implant reconstructions, 102 underwent pedicle TRAM flaps and 61 chose free TRAM flaps. For general satisfaction, significant effects in the regression were noted for procedure type ($p=0.033$) and preoperative activity level ($p=0.034$). Specifically, patients choosing TRAM reconstruction (over implant procedures) and women with higher preoperative activity levels were significantly more generally satisfied. General satisfaction did not differ significantly between pedicle and free TRAM patients. Finally, patient age and timing of reconstruction had no significant effects on general satisfaction.

In the logistic regression for aesthetic satisfaction, TRAM patients scored significantly higher than women undergoing implant reconstructions ($p=0.0001$). Furthermore, pedicle TRAM patients were significantly more satisfied aesthetically than those choosing free TRAM flaps ($p=0.047$). The other independent variables in our analysis (timing of reconstruction, patient age and preoperative activity level) had no significant effects on aesthetic satisfaction.

Conclusions: Choice of procedure appears to have significant effects on both general and aesthetic patient satisfaction following breast reconstruction. In this study, autogenous tissue reconstructions produced higher levels of patient satisfaction compared with implant techniques. By contrast, timing of breast reconstruction and patient age do not appear to be significant determinants of patient satisfaction with these procedures.

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ATTACHMENT SEVEN

Abstract: "Objective Assessment of Aesthetic Outcomes in Breast Reconstruction". American Society of Plastic and Reconstructive Surgeons, Annual Meeting, New Orleans, Louisiana, October 26, 1999.

ABSTRACTS MUST BE RECEIVED BY FEBRUARY 22, 1999.
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Title:

OBJECTIVE ASSESSMENT OF AESTHETIC OUTCOMES IN BREAST RECONSTRUCTION

☒ 6 minute ☐ 3 minute ☐ video ☐ poster

Introduction: Outcome studies of breast reconstruction have traditionally relied upon *subjective* measures of aesthetic results, which have poor reliability (Lowery, 1996). Our goal was to compare aesthetic outcomes of implant and TRAM reconstructions using objective methodologies previously described by our group.

Methods: Standardized anterior and lateral photos were obtained two years postoperatively from 27 implant and 57 TRAM reconstruction patients. Breast symmetry was evaluated using 21 standard breast measurements derived from Penn (1955) and Smith (1986). Using a slide scanner and image analysis software (Johnson, 1994), photographs were converted to digital images and breast dimensions quantified. Dependent variables of symmetry were calculated as the sum of absolute differences in measured dimensions between breasts, divided by the sum total of all normal breast (or right breast, in the case of bilateral reconstructions) dimensions. Statistical analysis was performed using analysis of variance, with procedure type as the independent variable.

Results:

Data set analyzed	Type of reconstruction	N	Mean Difference†
Frontal subset*	Implant	27	4.52%
P<0.0001	Pedicle TRAM	30	2.36%
	Free TRAM	27	2.42%
All frontal dimensions	Implant	16	3.88%
P=0.4363	Pedicle TRAM	27	3.51%
	Free TRAM	22	4.04%
All lateral dimensions	Implant	10	10.4%
P=0.0139	Pedicle TRAM	15	6.02%
	Free TRAM	11	8.36%
All dimensions	Implant	10	4.91%
P=0.0277	Pedicle TRAM	15	3.15%
	Free TRAM	11	4.21%

*Frontal measurements which do not include nipple

† Difference in symmetry expressed as a percentage of summed normal breast dimensions

Conclusions: Using objective measures of aesthetic outcome, we found that for all measured groups, TRAM flaps offered superior dimensional symmetry. These differences were statistically significant in three of the four dimensional groups. Furthermore, pedicle TRAM reconstructions produced greater symmetry than free TRAM flaps in all measured groups.

Please list words for indexing if selected: Breast Reconstruction, Outcomes Research,
Aesthetic Outcomes in Breast Reconstruction

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ATTACHMENT EIGHT

Abstract: “Complications and Patient Satisfaction Following Breast Implant Reconstruction With and Without Radiotherapy”. American Society for Therapeutic Radiation Oncology, Annual Meeting, San Antonio, Texas, November 3, 1999.

Complications and Patient Satisfaction Following Breast Implant Reconstruction With and Without Radiotherapy

Krueger E¹, Wilkins EG¹, Strawderman M¹, Cederna P¹, Goldfarb S¹, Vicini FA², Pierce LJ¹
University of Michigan, Ann Arbor MI¹; William Beaumont Hospital, Royal Oak MI²

Purpose: To prospectively compare the rates of complications and patient satisfaction among breast cancer patients treated with mastectomy and a tissue expander/implant with and without radiotherapy.

Materials and Methods: As part of the Michigan Breast Reconstruction Outcome Study (MBROS), breast cancer patients undergoing mastectomy with reconstruction were prospectively evaluated with respect to complications, general patient satisfaction with reconstruction, and aesthetic satisfaction. Included in this study were a cohort of women who chose reconstruction using an expander/implant. A subset of these patients received radiotherapy either before or after reconstruction. At one and two years post-operatively, a survey was administered which included seven items assessing both general satisfaction with their reconstruction and aesthetic satisfaction. Responses ranged from 1, indicating high satisfaction, to 5, reflecting low satisfaction. Only patients responding with a 1 or 2 for all of the items in the subscale were scored as "satisfied". Complication data were also obtained at the same time points using hospital chart review. Any radiotherapy patients identified in the U of M Radiation Oncology data-base not included in the MBROS study were also included in the complication analysis.

Results: Seventy-seven patients received an expander/implant reconstruction after mastectomy. Eighteen (23%) received radiation. For the radiotherapy patients, 50% received RT preceding the implant and 50% were irradiated following implant placement. The median dose delivered to the irradiated reconstructed breast, including boost, was 60 Gy (range 50.0-66.0 Gy) in 1.8 to 2.0 Gy fractions.

With a median follow-up of 31.5 months from the date of surgery, the rates of complications were compared. Complications occurred in 72% (13/18) of the RT patients compared to 36% (21/59) in the no RT group ($p=0.006$). The most common complications were infection and contracture, with infection occurring in 44% (8/18) of women with RT and 24% (14/59) without RT ($p=0.13$), and capsular contracture in 22% (4/18) and 10% (6/59), respectively, with and without RT ($p=0.23$). The rates of explantation varied significantly by group, with a 44% (8/18) explantation rate in the RT group versus 7% (4/59) in the no RT ($p=0.0006$).

Sixty patients completed the satisfaction survey. For general satisfaction, 45% in the RT group were satisfied with their reconstruction compared to 58% in the no RT group, $p=0.51$. For aesthetics satisfaction, 36% of women in the RT group were pleased with their result compared to 24% without RT, $p=.46$. When a multivariate logistic regression analysis was performed for the general satisfaction and aesthetics outcomes including both radiotherapy and complications, neither RT nor the rate of complications were found to significantly impact either endpoint. For general satisfaction, the odds ratio (OR) was .67 (CI 0.18-2.59) for RT/no RT versus .53 (CI 0.18-1.58) for complications/no complications; for aesthetics, the OR were 1.57 (CI 0.38-6.51) and 1.83 (CI 0.56-5.94), respectively.

To offset potential bias for patients not completing the survey, we re-analyzed satisfaction data assuming "dissatisfaction" scores for surveys not completed. For general satisfaction, the OR was 0.57 for RT/no RT and 0.41 for complications/no complications. For aesthetics, the corresponding ratios were 1.0 and 1.3, respectively.

Conclusion: Irradiated patients had a higher rate of expander/implant reconstruction failure and complications than non-irradiated patients. Despite these differences, our pilot data suggest that both general satisfaction and patient aesthetic satisfaction were not significantly different following radiotherapy compared to patients who did not receive RT. Although statistical power was limited in the present study and larger patient numbers are needed to validate these results, this study suggests a comparable cosmetic outcome in RT versus no RT patients in women who undergo successful implant reconstruction.

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ATTACHMENT NINE

**Printed copy of the new University of Michigan Breast
Reconstruction Educational web site that includes data from
the Michigan Breast Reconstruction Outcome Study.**



Welcome to the MBROS Consumer's Guide to Breast Reconstruction!

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Breast reconstruction is the process of making a new breast after a woman has had her breast(s) removed due to breast cancer. This web site should give you understandable, up-to-date information about breast reconstruction options. We hope this information answers many of your questions, lets you know what to expect, and helps you make a decision that you feel good about.

If you are a new breast cancer patient, we suggest that you look at these pages first:

1. [Should you have breast reconstruction?](#)
 - o [Non-surgical breast replacement options](#)
 - o [Surgical breast reconstruction options](#)
2. [When should you have breast reconstruction?](#)
3. [Breast reconstruction options:](#)
 - o [Implants](#)
 - o [Natural Tissue Reconstruction](#)
 - o [Options Summary Table](#)

After you have decided to have breast reconstruction, you may be interested in these pages:

1. [Issues to Consider About Breast Reconstruction:](#)
 - o [Who will do my breast reconstruction?](#)
 - o [Who will pay for my breast reconstruction?](#)
 - o [Should I have mammograms after breast reconstruction?](#)
2. [Additional surgical options after breast reconstruction \(Options Summary Table\)](#)

Additional sources of information available on this site include:

- [Chat Room](#)

- Resource List

(You can also download a printable version of the information contained in this web site if you would like to read it as a booklet.)

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 - [MBROS Study Results: Mammography After TRAMs](#)

7. Comparison of Reconstruction Options (Options Summary) [table]

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 - [Breast Reduction](#)
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- [Comparison of Surgical Options After Reconstruction \(Options Summary\) \[table\]](#)

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When you lose a breast to cancer, it is comforting to think you can replace it and look and feel almost normal again. However, treating the cancer and getting back to a healthy life should always be your first concerns.

If you are able to have breast reconstruction, make your decision about whether to have reconstruction, when to have reconstruction, and what kind of reconstruction to have based on what is best for you. A new breast is unlikely to change your life or make others treat you differently. Your doctor, family, and friends may offer suggestions, but you are the one who is going to have to live with your choice every day. Try to make a decision that you can feel good about for a lifetime.

How Will Breast Reconstruction Affect My Life?

Breast reconstruction may help you to feel better about your body: you may feel more "normal," "balanced," and feminine. It may also help you to be able to wear more kinds of clothes with convenience and comfort.

Some women are afraid that if the breast cancer returns, it will be harder to detect the tumor through a reconstructed breast than through a mastectomy scar. However, there is no need to fear difficulties with cancer detection. Current evidence indicates that it is no more difficult to find and treat cancer through a reconstructed breast than it is through a mastectomy scar.

If you are thinking about breast reconstruction and are interested in breastfeeding your children, you should know that you cannot breastfeed from a reconstructed breast. The parts of the breast that deliver milk are the most likely parts to develop cancer and are therefore removed during the mastectomy.

Having breast reconstruction may cause you some inconvenience during the period after the surgery. It will take time to recover, and there may be additional treatments or follow-up surgeries. Depending on which kind of breast reconstruction you choose, you may need up to six months or a year to fully return to your normal life.

Only you can decide whether the mental and physical benefits

of having a new breast are worth the costs of having the surgery.

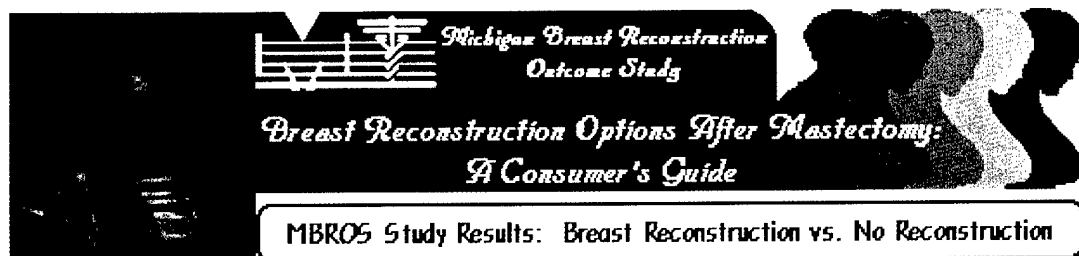
Advantages of Breast Reconstruction:

- You may feel more "balanced," in terms of both breast weight and looks.
- Your body may feel more "normal," in and out of your clothes.
- You may be able to wear more kinds of clothes, possibly even low cut clothes like tank tops and bathing suits.
- You may feel more feminine and attractive.
- You may not be reminded of the cancer by having only one breast.

Disadvantages of Breast Reconstruction:

- Regardless of the type of reconstruction you have, you will need more surgery, with all of the inconvenience and potential problems that come with it.
 - You may need more time to heal.
 - You may need to take more time off from work or from your family responsibilities.
 - There may be more scars.
 - There may be extra problems after the surgery, such as infection, swelling, or delayed healing.
- If you do not have insurance, it may be costly.
- You won't know how the new breast will look until after it is finished.
- The new breast, no matter how good it is, will never exactly match your natural breast.
- In rare cases, there may be problems that come and go for years afterwards, like infections or breast implant complications.

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Breast Reconstruction vs. No Breast Reconstruction: And the Study Says...

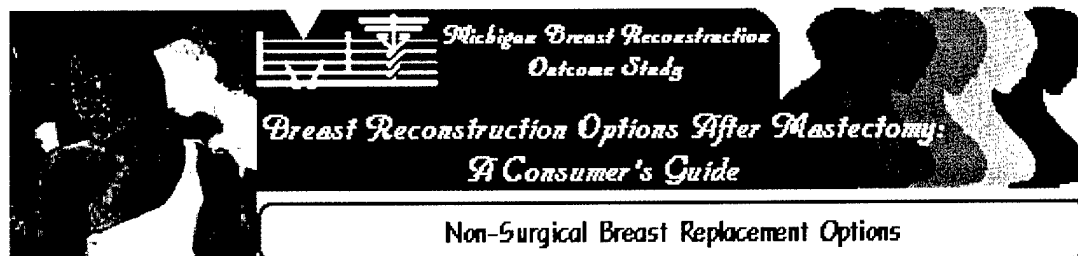
The Michigan Breast Reconstruction Outcome Study (MBROS) reports that a group of 250 breast reconstruction patients showed statistically significant psychological and functional gains one year after their operations, regardless of which type of breast reconstruction procedure they chose (1). They improved in mental health, emotional well-being, energy level, ability to perform normal daily activities, and satisfaction with the way their breasts looked.

This study does not include a control group of breast cancer patients who did not have breast reconstruction for comparison. However, other studies have shown that patients who undergo breast reconstruction have better body images, self esteem, and sexual functioning than patients who do not have reconstruction (2-5).

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Many women choose not to have breast reconstruction because:

- they feel comfortable living with only one breast.
- they don't want to have more surgery;
- their partners or families do not think reconstruction is necessary;
- there is no plastic surgeon who does breast reconstruction in their area.

If you choose not to have breast reconstruction, you can:

- Live without a breast replacement, or
- Get a prosthesis (false breast).

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Some women who choose not to have reconstruction may wear a false breast (prosthesis) or stuff their bras with padding. Others choose to do nothing. The side of the chest with the mastectomy simply remains flat, and the mastectomy side of the bra remains empty.

Advantages of No Replacement:

Wearing no replacement may be:

- simpler
- more convenient
- more comfortable

Disadvantages of No Replacement:

- Some women may feel unbalanced with only one breast.
- It may be harder to keep your posture straight because of the imbalance.
- It may be harder to wear some kinds of clothes with only one breast.

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A prosthesis is a breast form you can use under clothing to recreate the breast. Some women choose to use a prosthesis until they have breast reconstruction, while others use prostheses for life.

Where Do I Get a Prosthesis?

Prostheses can be purchased at surgical supply stores, pharmacies, custom lingerie clothing shops, or a private home service.* Contact the Reach to Recovery program of the American Cancer Society for information about which stores in your area sell prostheses (telephone 1-800-ACS-2345). You may want to contact the stores first to ask if they offer a trained fitter. Fitters know how to take your measurements so that the prosthesis fits your chest and matches your other breast. They can also show you how to wear it. When you have the prosthesis fitted, consider trying on samples under a variety of your own clothes.

*If you live in the Ann Arbor, Michigan area, you may want to try Personal Touch. They have a great selection of prostheses and post-mastectomy wear, a trained nurse fitter, and a web site with lots of good information on prostheses, local breast cancer support groups, and caring for yourself after breast cancer.

How Does the Prosthesis Stay in Place?

Special bras, lingerie and bathing suits are designed for breast cancer survivors. They are available from Nordstrom, Sears, Land's End, JC Penney, or American Cancer Society catalogs, as well as department stores and smaller specialty shops. The clothing comes with a pocket to hold the prosthesis, or you can have pockets sewn into the suits or bras you already own. This helps keep the prosthesis from popping out during swimming or other physical activities. One product comes with adhesive Velcro patches to attach the prosthesis to the upper part of your chest. This allows you to go bra-less or wear a regular bra. Many active women and athletes choose this model. (Since some women are allergic, ask the store to let you take home and try a sample of the adhesive before buying the whole product.) The adhesive lasts from three to five days and the prosthesis can

even be worn while swimming or in the shower.

How Do I Choose a Prosthesis?

There are many shapes, sizes and materials of prostheses. The ideal product has the shape, weight, motion, and balance of your natural opposite breast. You'll probably want to get more than one type of prosthesis. Before you go into surgery, consider contacting your local Reach to Recovery program of the American Cancer Society (1-800-ACS-2345). They provide a free temporary prosthesis to all women who are undergoing mastectomy. You can adjust the temporary prosthesis by filling a cloth cover with as much fiberfill as you need to match the other side.

While this temporary model is helpful for the initial recovery period, you will probably want to buy a longer-lasting prosthesis at some point. There are two main types. A lightweight style (made of polyfill or foam) is also good for the initial post-surgery recovery period. It can be used later for warm weather activities or times when you want less weight. This type is machine washable.

The second type is made of silicone. Most women prefer this style, because it is more lifelike. Two shapes are available: asymmetrical (one for the left side, one for the right) and symmetrical, a pear shape worn sideways to fill out the side, or straight up for fullness and cleavage. Silicone is closer to the consistency and weight of a natural breast. You may find the weight a bit tiring, but it can help balance the other breast and keep your posture straight. Silicone products are hand washable. Many prostheses are shaped to include a nipple on the front.

Prostheses also come with different kinds of covers. Most have some type of cloth cover, like soft cotton. Others come with a latex cover. Some brands now offer a cloth pad on the back to absorb perspiration and keep you cooler. Ready-made products come in many sizes; you choose the one that matches your natural side. It's worth taking the time to find one that matches your other breast and is comfortable. If you really want to splurge, you can buy a custom-made prosthesis that is made specially for you, to fit the contour of your body and match your other breast.

How Much Will It Cost?

Prices of silicone prostheses range from \$200 to \$500. Foam and fiberfill prostheses usually cost less than \$100. Cost depends mostly on quality and brand. A custom-made prosthesis will cost much more. If you want your health insurance to

reimburse you, be sure to get a prescription from your doctor for the prosthesis. Prostheses last from two to five years. (Swimming pool water, salt water, and hot tubs will damage silicone prostheses.) Most insurance coverage pays for two bras with a prosthesis pocket per year and a new prosthesis every two years. If you do not have insurance, check with the American Cancer Society. Many offices give away free prostheses that stores have donated.

Advantages of Prostheses:

- Prostheses may give you a more natural shape under clothes.
- Prostheses may give a more "balanced" look.
- Prostheses do not require surgery.
- If your natural breast size changes, you can buy a new prosthesis.

Disadvantages of Prostheses:

- You may be less comfortable in revealing clothes than if you had reconstructive surgery.
- A prosthesis may be heavy, feel hot, and move around inside the bra.
- You may need to wear a special bra so the prosthesis doesn't fall out (or buy a model with adhesive).
- It may be less convenient to do certain things, such as playing active sports, than if you had reconstruction or did not replace the breast.
- It is tough to scratch an itch underneath a prosthesis.
- Prostheses do not change size with weight gain (although you can buy a new prosthesis to match the change in your natural breast).

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Many women choose to have breast reconstruction. Some women feel more natural and balanced with a reconstructed breast.

There are two major kinds of breast reconstruction:

- [Implant Reconstruction](#)
- [Natural Tissue Reconstruction](#)

Some practical questions you may want to think about include:

- Should my reconstruction be immediate or delayed?
- Who will do my reconstruction?
- Who will pay for my reconstruction?
- Should I have mammograms after my reconstruction?

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Your breast can be surgically reconstructed by putting in an artificial breast mound, known as an implant.

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*Breast Reconstruction Options After Mastectomy:
A Consumer's Guide*

Implant Reconstruction

How is Breast Reconstruction Using Implants Performed?

Synthetic implants are usually teardrop-shaped pouches that are placed under a layer of chest muscle to create the shape of a breast. The outside of the implant is made of silicone and it is filled with silicone gel or saline. Saline is another word for salt water. Silicone is an artificial material that feels like natural breast tissue.

The process of breast reconstruction using implants may involve one or two stages, often depending on the individual patient's breast size. For smaller breasted women, a single stage reconstruction may be possible. With this approach, the plastic surgeon places the silicone gel or saline implant in a pocket beneath the skin and muscle layers, at the location of the new breast. This surgery is usually performed through the old mastectomy scar.

Most commonly, implant breast reconstruction is carried out in two stages. The first stage consists of placement of a device called a "tissue expander." An expander is a silicone-walled pouch that resembles an empty balloon with a small valve in its front wall. This valve allows the surgeon to fill the implant with saline in the weeks following this initial operation. During the second stage, the tissue expander is replaced with an implant.

Tissue Expanders



Photo courtesy of McGhan Medical Corporation

ONE PATIENT'S STORY OF HER IMPLANT RECONSTRUCTION

"Once it was

During the first surgery, the tissue expander is placed in a pocket beneath a chest muscle (the pectoralis major) and the overlying skin. The tissue expander must be used to enlarge the implant pocket to accommodate the size of the implant needed to match the opposite breast. This initial surgery takes approximately one to two hours. At the end of the surgery, the side of the chest undergoing reconstruction will still be flat.

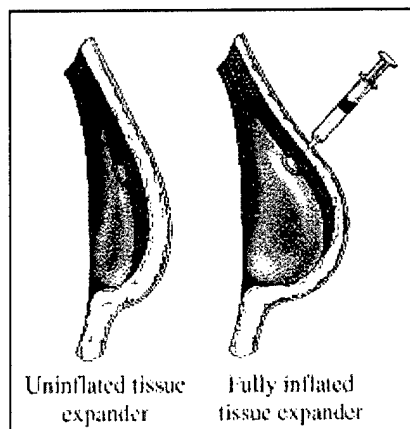
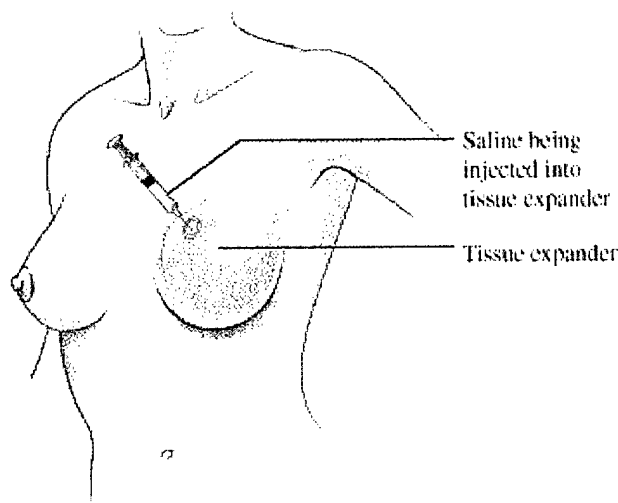
determined that I would be having a mastectomy, I had to decide which type of reconstruction I wanted. I chose an implant. At the time my breast was removed, an expander was placed under the pectoral muscle. The expander was a balloon with a port to accommodate injections of saline to stretch the skin and muscle so the implant could be placed.

After my incision healed, the injections were started. I was really afraid it would hurt, but there was no pain, just a feeling of pressure. It was about three months after surgery, and it took four or five visits to expand the skin to the size the doctor wanted so both breasts would be the same size after the implant.

Six months later, in June, the expander was removed and the implant put in place. This was done under general anesthetic and I spent the night in the hospital. Except for the normal discomfort of surgery, the worst part of both surgeries was the removal of the drain

Depending on your doctor's recommendations, this procedure can be performed on an outpatient basis or may require a hospital stay of one to two days.

Approximately 10 to 21 days following placement of the tissue expander, the process of tissue expansion will begin. Every one to two weeks, you will visit your plastic surgeon. During these 20- to 30-minute visits, approximately two to four ounces of saline (salt water) will be injected through the overlying skin into the valve located on the front wall of the tissue expander.



With each visit, the tissue expander is gradually inflated. The growing tissue expander enlarges the pocket, inducing growth of the overlying skin. In essence, this tissue expander grows the skin for the new breast. While the expansion process causes slight soreness or discomfort in some women, others report simply a feeling

of "tightness" for several days following each expansion.

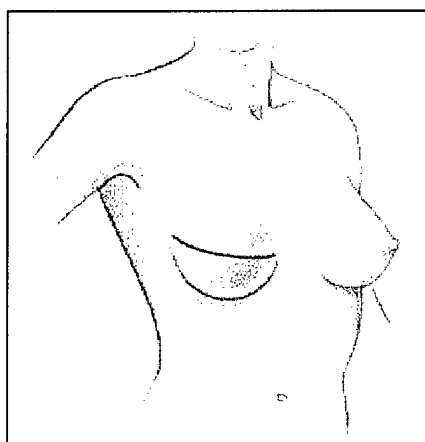
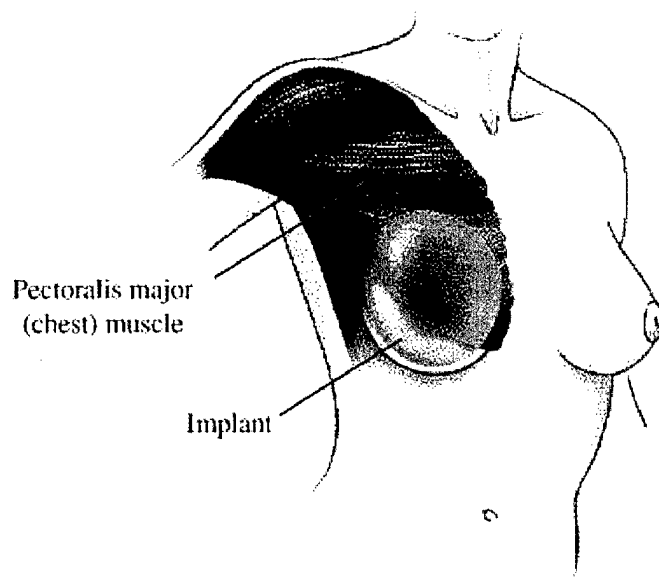
Approximately one to three months after the tissue expander has reached the correct size, you will undergo a second operation. During this surgery, the expander is removed and an implant is inserted in its place. The surgery lasts about one to two hours and is followed by a hospital stay of four to 24 hours.

Saline-Filled Implants



tube. It was done quickly, but it hurt a lot. I did not choose to have nipple reconstruction, but with a fiberfill bra, no one can tell I ever had my breast removed."

Photo courtesy of McGhan Medical Corporation

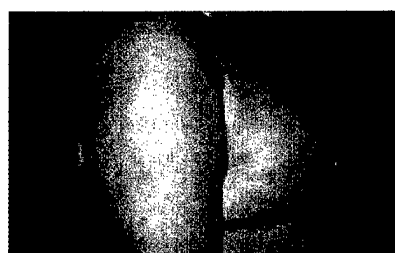
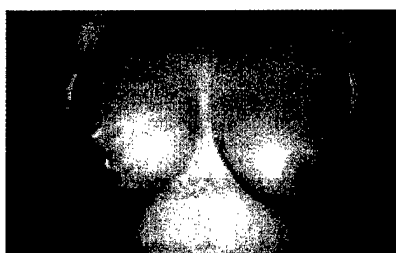


Size and location of scar may vary

In some smaller-breasted women, an implant may be placed in a space directly under a layer of chest muscle. This is done in a single operation that takes about one to two hours. Since a small implant is used, the surgeon may be able to insert it without additional operations to stretch the skin and muscles of the chest wall.

The implant is placed under a layer of muscle, rather than directly under the skin, to ensure the most natural shape and feel of the reconstructed breast. This also helps to reduce formation of scar tissue around the implant.

Finished Implant Reconstructions:



▲
Saline-Filled Implant, Front View
(with nipple reconstruction)



▲
Saline-Filled Implant, Front View

Saline-Filled Implant, Side View
(with nipple reconstruction)



Saline-Filled Implant, Side View

MY IMPLANT: ONE WOMAN'S STORY

"I had the implant. Every week I went in and they inserted more saline. Then once it got up to size, then I had the surgery to have the implant put in. But they had to custom make the implant. They did not have one on the shelf that was, it only went up to like a B+, and I'm a D. I had the choice of having that done or having the other breast augmented. And I chose not to do that; there was nothing wrong with the other one, it was clean, and I just didn't want to mess with it. I chose to have an implant because I have adhesive sensitivity. I broke out in blisters from the adhesive [from the temporary prosthesis] when I was first going through the [mastectomy]. So I did not want to attempt it. And because of being large-breasted, I was having problems with my shoulder coming in, because there was nothing there to support. So my husband and I discussed it and I said I wanted to go through the reconstruction. [I decided I did not want to have a TRAM because] I had been through a biopsy, lumpectomy, then two weeks later a mastectomy, and so I had had like two months of nothing but getting over surgery. [A TRAM is] like two major surgeries at once and it was going to be almost a week in the hospital and everything, and I had been through so many surgeries already that I just didn't want to do that. So I went for the implant. And then I also had the nipple reconstruction.

It was worth going through the little bit of pain that I had. Going through the tissue expansion was not as bad as what I thought. And once the [implant] was in, I had about a week of discomfort, and I found that I could not lay flat on my back for a couple of nights, because of the weight would push to one side or the other, and I would be in a lot of pain. Having the expander in there was not like having the actual [implant]. You knew exactly where the fill valve was, and in me, it moved around. So it sometimes was at one side or the other. And it

could get uncomfortable if it got in the wrong position. But I was able to manipulate it so that I would be comfortable again.

It came out very good. For having an [implant] in there, it not being a TRAM flap, and [for] the size that I am, I really got very good results. [If I had it to do over again], I might have them make it just a little smaller. Because the one thing that you have to think about is that if somewhere down the line you lose weight, one place that you lose weight is your breasts. I lose weight in the other one, but I don't lose weight in that one. It doesn't change. Somewhere down the line if I lost more weight, then I would have to pad the other side to match. [What's my advice to other women considering breast reconstruction?] Investigate it, and be sure that you get an experienced surgeon, one that has done a lot of breast reconstructions. Don't just go to any plastic surgeon.

I would have reconstruction again. It's more comfortable. I have a cleavage. When I bend over, it looks very normal, you can't tell anything. When I had to wear a prosthesis in there, I never wore anything that had a V-neck or a round neck, that if I did happen to bend over, and somebody happened to look, they would see my prosthesis. I always wore very high-necked type things. I wear looser clothes now. I don't wear anything really tight, because if I did, then yes, it would be noticeable, because it is flatter than what a normal breast is, even with the nipple reconstruction. But otherwise, I would have it done again, no question.

People that meet me today would have no idea that I have ever had breast cancer or reconstruction. The only ones that see the scar are me and my husband, and the doctor. It's under your clothes. And the scars do lighten over time. So I have been very satisfied with it. It's just much more natural. And I don't have to worry about fitting the prosthesis in and adjusting it and everything. It's there, it's part of me now."

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Should I Have a Silicone Gel or a Saline Implant?

Many plastic surgeons believe that silicone gel-filled implants have a more natural look and feel than saline implants. Silicone gel has a texture that is very similar to natural breast tissue. Saline implants, on the other hand, do not feel as soft.

However, silicone gel also has certain disadvantages. For example, silicone gel implant ruptures are harder to detect. When saline implants rupture, they flatten visibly. When silicone gel-filled implants leak, the breast often looks and feels the same. As a result, silicone gel may begin leaking into surrounding areas of the breast unnoticed. Also, replacing a ruptured silicone gel implant is more difficult than repairing a saline implant. This is because the silicone gel that has leaked outside of the implant should be removed (if possible).

There have been some reports in the media of various health problems as a result of silicone gel. In these reports, silicone gel has been associated with lupus, rheumatoid arthritis, scleroderma, neurological disorders, and other conditions. Silicone gel-filled implants were removed from the market to give scientists time to study the effects of silicone. However, researchers have found no evidence thus far supporting the connection between silicone gel breast implants and medical problems. Women who have silicone gel implants appear to have the same risk of disease as women who do not. Because of this information, silicone gel implants are beginning to be offered again by certain doctors. Still, the vast majority of breast reconstruction is done with saline-filled implants. You should be aware that even the saline implants are made of a silicone pouch filled with saline.

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Implant surgery requires a shorter hospital stay and shorter recovery time compared with most other reconstruction options.

Because this approach requires less extensive surgery than other reconstruction methods, usually less recovery time is necessary. If you choose to have immediate reconstruction, you will likely stay in the hospital for one to two days after the combined mastectomy and tissue expander or implant surgery. When the reconstruction is delayed, your hospital stay will probably be about 24 hours. If you have a tissue expander, the second operation, in which the tissue expander is replaced with an implant, will require a hospital stay of four to 24 hours. Although every woman's recovery time is different, most women will be able to resume many of their regular activities after one week. After implant placement surgery, three to four weeks may be required before patients can perform more strenuous activities or return to work.

Implant surgery produces relatively predictable breast shapes in most women.

Since implants are made in pre-set shapes, it may be easier (compared with flap reconstructions) to predict what the reconstructed breast will look like. Therefore, you may have more realistic expectations about the surgery.

Implant surgery leaves fewer scars.

Reconstruction with implants usually results in only one or two scars around the breast. Often the mastectomy scar is used as the site of the new incision so you will have no additional scars after the reconstruction.

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Implant surgery may give a less natural breast shape.

It may be more difficult to ensure that both breasts are the same shape when implants are used. Implants do not allow the same degree of sculpting and shaping as natural tissue. As a result, the breast with the implant and the natural breast may not look exactly the same. Implants also do not feel completely natural to the touch.

Implant surgery may be time consuming and inconvenient.

If a tissue expander is needed, additional surgery and frequent doctor visits will be necessary. You must consider if you have the time and patience to undergo another surgery, hospitalization, and recovery period. You also need to think about whether you can attend doctor appointments every one to two weeks.

The results of implant surgery may not be immediate.

If a tissue expander is needed, you will not wake up from the initial surgery with a new breast. This can be disappointing if you are eager to see your new breast. If a tissue expander is required, it takes four to six months for breast reconstruction to be completed. During this time, one breast is bigger than the other, creating a "lopsided" effect. This may make you feel awkward or uncomfortable with your body. It may also limit the clothing you wear and the activities in which you participate. You may choose to wear a prosthesis or pad your bra to make your breasts the same size. However, this may not work if you are especially active.

If you have had radiation therapy, your skin may not respond well to the tissue expander.

Radiation tends to cause scarring in the radiated skin on your chest. This skin may not stretch well during tissue expansion, making the process more difficult.

Complications with the implant may develop.

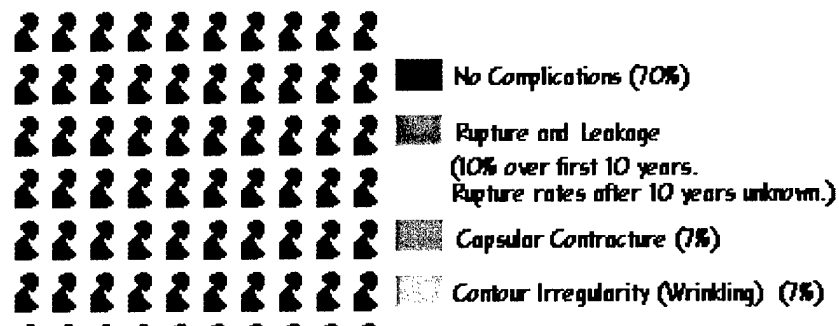
About two to four women in 100 develop an infection near their surgical incision soon after the operation. Another two in 100 may experience bleeding ("hematoma") or fluid collection ("seroma") under the breast skin after surgery.

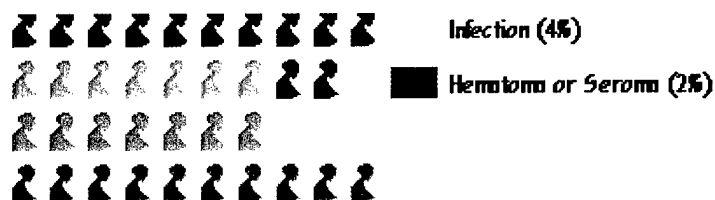
Implants may also develop complications over the long term.

The most common complication is leakage or rupture. This happens in approximately 10% of cases over the first 10 years. (No data yet exist to track the life of an implant after the first 10 years.) When this occurs, the implant must be removed or replaced. This surgery lasts from 30 minutes to 1 hour. It may be done on an outpatient basis or require an overnight stay. If the implant was filled with silicone gel, more extensive surgery, lasting at least one hour per implant, may be needed to remove as much silicone as possible from the breast area.

The second most common complication is encapsulation or "capsule formation." Scar tissue forms on the outside of all artificial implants when placed in the body. Usually, this does not pose a problem. However, in approximately 5-10% of cases, too much scar tissue forms. This may occur more frequently with silicone implants than with saline implants. The scar tissue may cause pain and discomfort and make the implant feel hard to the touch. When this happens, surgery may be necessary to break up or remove the scar tissue. It may also be necessary to remove or replace the implant. Capsules can form at any time from a few weeks to many years after the implants are inserted.

In about 7 cases out of 100, the implant shifts relative to the breast tissue sometime after the surgery, causing a "wrinkle" or "dent" in the shape of the final breast reconstruction ("contour irregularity").





Complication rates adapted from Handel et al,
Plastic and Reconstruction Surgery 1995; 96:1521.

Silicone gel-filled implants are not available at all hospitals.

There have been some reports in the media of various health problems as a result of silicone gel. In these reports, silicone gel has been associated with lupus, rheumatoid arthritis, scleroderma, neurological disorders, and other conditions. Silicone gel implants were removed from the market to give scientists time to study the effects of silicone gel. However, researchers have found no evidence thus far supporting the connection between silicone gel breast implants and medical problems. Women who have silicone gel-filled implants appear to have the same risk of disease as women who do not. Because of this information, silicone gel implants are beginning to be offered again by certain doctors. Still, the vast majority of breast reconstruction is done with saline-filled implants. You should be aware that even the saline implants are made of a silicone pouch filled with saline.

Implants do not change to match changes in body weight.

Implants do not change size or shape. This means that the size and shape of your reconstructed breast will also remain the same, regardless of changes that may occur elsewhere in your body. Consequently, if you lose or gain weight, your breasts may seem disproportionate to your new body shape.

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Michigan Breast Reconstruction
Outcome Study

Breast Reconstruction Options After Mastectomy: A Consumer's Guide



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■ No Complications (70%)

■ Rupture and Leakage
(10% over first 10 years.
Rupture rates after 10 years unknown.)

■ Capsular Contracture (7%)

■ Contour Irregularity (Wrinkling) (7%)

■ Infection (4%)

■ Hematoma or Seroma (2%)

Complication rates adapted from Handel et al,
Plastic and Reconstruction Surgery 1995; 96:1521.

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The silicone shell of the implant may break, causing the saline or silicone gel inside to leak out into the surrounding breast tissue. This happens to about 10% of women during the first 10 years after implant surgery. (No data exist to track the frequency of ruptures after the first 10 years.) Another surgery must then be done to remove or replace the implant.

Capsular Contracture

Too much scar tissue may form around the outside of the implant, causing discomfort and making the breast feel hard. This can happen at any time, from several weeks to several years after the surgery. Another surgery must then be done to remove or replace the implant.

Contour Irregularity (Wrinkling)

The implant may shift relative to the breast tissue, causing a "wrinkle" or "dent" to form in the shape of the finished

breast reconstruction.

Infection

The surgical incision may become infected soon after the surgery.

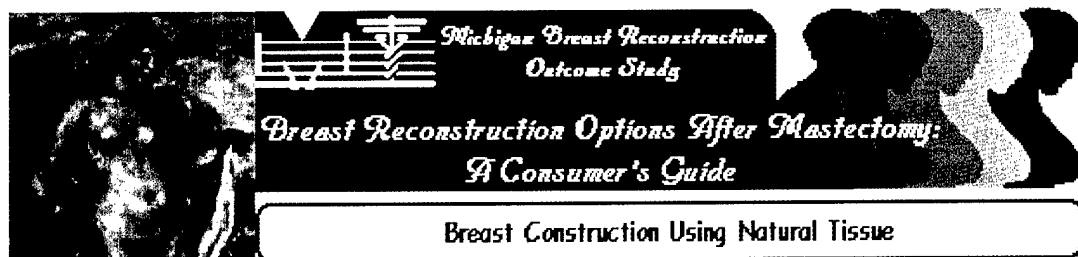
Hematoma or Seroma

A pocket of blood ("hematoma") or blister fluid ("seroma") may form under the breast skin soon after the surgery.

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Your own body tissue can be used to recreate a breast.

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The most common kind of natural tissue reconstruction is the TRAM, in which tissue from the abdomen is used to create the breast.

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☒ TRAM Flap Reconstruction

TRAM (Transverse Rectus Abdominis Muscle) Flap Reconstruction

This operation uses tissue from your lower abdomen to make a new breast. It can either be done with the tissue remaining connected and tunneled under your abdominal muscle and skin ("pedicle" TRAM) or with the tissue disconnected from the abdomen and reattached on the chest ("free" or microsurgical TRAM).

How is TRAM Flap Reconstruction Done?

There are two types of TRAM reconstruction surgery: the "tunneled" (pedicle) method and the "free" (microsurgical) method. For either method, tissue is taken from the lower abdomen. The doctor will determine if you are able to have a TRAM, depending upon availability of donor tissues. For example, the doctor may not be able to use the abdomen tissue to reconstruct a breast if you have had previous surgery in that area. If you are a smoker, the doctor may choose not offer the TRAM reconstruction procedure at all. When discussing these reconstructive options with your doctor, be sure to mention other health problems that you may have. Also be sure to mention your lifestyle and what kinds of activities you want to be able to do after the surgery. These other issues will be very important in determining if this method of reconstruction is right for you, and if it will be successful.

In the TRAM procedure, the skin, fat, and muscle of the lower abdomen are used to recreate the breast. This is some of the same tissue that is taken during a "tummy tuck" procedure.

1. Pedicle TRAM

In the pedicle ("tunneling") method of this procedure, this tissue is separated from its original location (without being completely disconnected), turned upwards, and tunneled under the abdomen. It is brought up and out through the mastectomy site (or scar depending on time of reconstruction). The tissue is then sculpted to look as much like the other breast as possible. The lower abdomen site is then sewn back together.

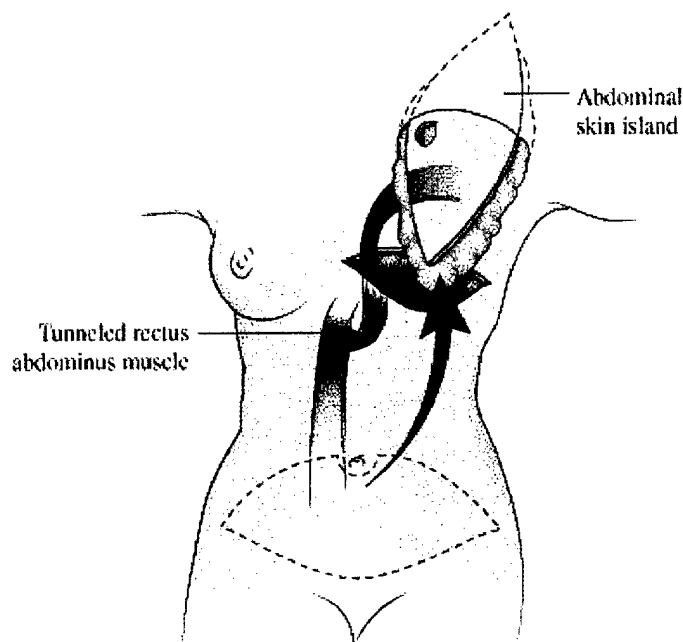
**"THOUGHTS
ON BREAST
RECON-
STRUCTION":**

ONE PATIENT'S STORY OF HER PEDICLE TRAM

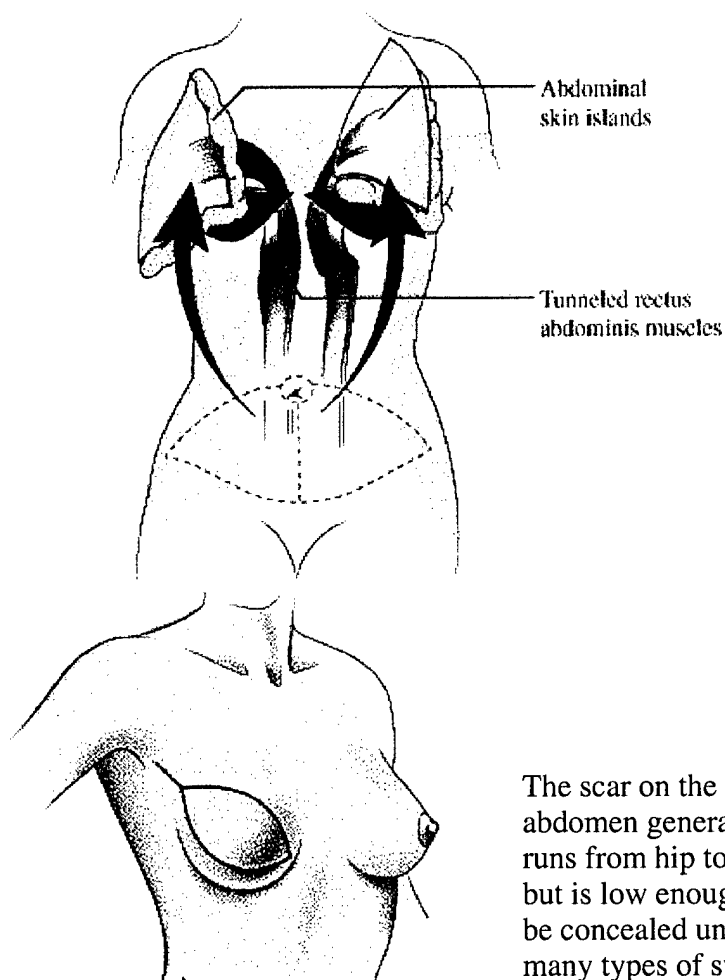
"At age 65, a year following my MRM [mastectomy], I elected to have a pedicle TRAM with a reduction/lift to the existing breast.

Surgery was in excess of nine hours. Due to a problem with an old appendectomy scar, there was concern that I might lose a small amount of transplanted skin on the underside of the new mound. Rather than return to surgery, it was decided to 'wait and watch', increasing my time in the hospital to ten days from the projected six or seven.

I was sore, not so much in the abdomen as the chest, but a



In case of a double mastectomy, the tissue on the lower abdomen may be used to make two breasts:



The scar on the lower abdomen generally runs from hip to hip, but is low enough to be concealed under many types of swim

PCA [Patient Controlled Analgesia] pump the first few days followed by oral pain medication kept me reasonably comfortable. As I live alone, I had a visiting nurse come the first five days I was home to change dressings. The problem spot took extra care in cleansing and medicating, but slowly healed and is now simply a slight indentation. It took three or four weeks to stand up straight and my stomach was quite tight. I went back to work in about four weeks.

A month or so later I discovered an area of lumpy tissue in the reconstructed breast. I returned to surgery to

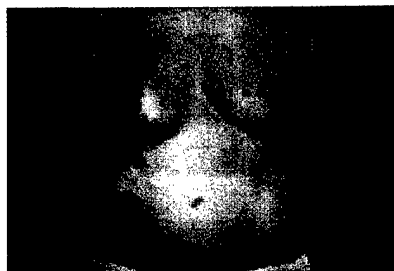


Breast scar may vary in appearance

or she can adjust the placement of the scar to make it less noticeable.

suits. If you tell the doctor which type of two-piece bathing suit you own, then he

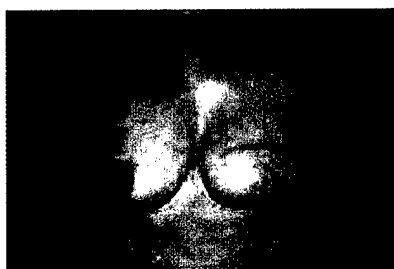
Finished Pedicle TRAM Flap Reconstructions:



Pedicle TRAM, Front View
(with nipple reconstruction)



Pedicle TRAM, Side View
(with nipple reconstruction)



Pedicle TRAM, Front View
(with nipple reconstruction)



Pedicle TRAM, Side View
(with nipple reconstruction)

MY PEDICLE TRAM: ONE WOMAN'S STORY

"I had an immediate [pedicle] TRAM at the time of my mastectomy on my right breast. I did not want anything other than me in my body. And I decided to do it at the time of the mastectomy because I just figured it would be better to get it all over with at one time rather than do one surgery and then the other. I really decided to have it done not because I'm a particularly vain person, but because I intend to live for a long time, and I'm optimistic about that, and I wanted my dresses to fit me correctly. Self image and well-being have a lot to do with recovery and survivorship. Another important reason for doing it, for me, [was] to assume as much normalcy in my life as was possible. That's important I think for me and for my husband and for my family. And it is wonderful for me not having to bother with a prosthesis. For me it's just so convenient to you know, jump in the shower,

have it removed (it was a benign fat necrosis) and decided to have nipple reconstruction at the same time. I have a long scar from hip to hip, but low enough to wear a two-piece bathing suit; the scars on my breasts don't show either. The new breast has continued to soften up and now feels much like the other one. I still don't have much feeling in my abdomen and none in the reconstructed breast.

Was it worth it and am I happy with the results?

Absolutely! It has made a world of difference in my mental state. The daily reminder that I had cancer when I looked in the mirror and saw that

jump in my clothes, and that's it. I have enough to take care of, and it's nice to not have to do anything extra. So far me, the surgery was well worth it.

The reconstruction itself far exceeded my expectations. The scars are very minimal. The skin of the breast itself was conserved. The thing that I like most about my TRAM is the way that my TRAM moves with the rest of my body. It moves like a breast, it's a little firmer than my other breast, but it feels very much like a breast, and so it feels very natural to me. Now what I liked least about the TRAM was what I'm experiencing currently are some back problems. I walk a little bit differently since my TRAM, and my balance is probably a little different. That I think is a result of how tight the abdominal muscles are and the fact that there's this constant pull forward, and to this day my abdominal muscles are quite tight. [It is important to have physical therapy immediately after the TRAM], just for stretching and mobility and stretching the abdominal muscles and reducing scar tissue.

The other part I think it's real important for women to know is that this is a difficult surgery. It's not a surgery that women should consider lightly. It is a difficult and long surgery, but for me one that was well worth doing. Initially the biggest irritation was the TRAM, and with the abdominal surgery was the drains. You know, having to empty the drains and deal with those being pinned to my clothing for a significant period of time, you know, a couple of weeks or so. What has always surprised me about this surgery is that it's not the TRAM that has really caused me much distraction. I've had really good arm mobility, and of course there's some loss of sensation because of the cutting of some of the nerves. But that I've adjusted to relatively easily. It's more the tightness in the abdomen, and the more limited abdominal strength which has been more noticeable for me. And that was something I really wasn't expecting to the degree that it exists.

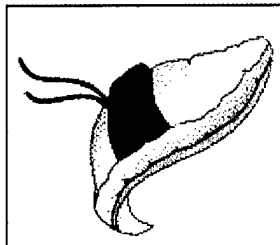
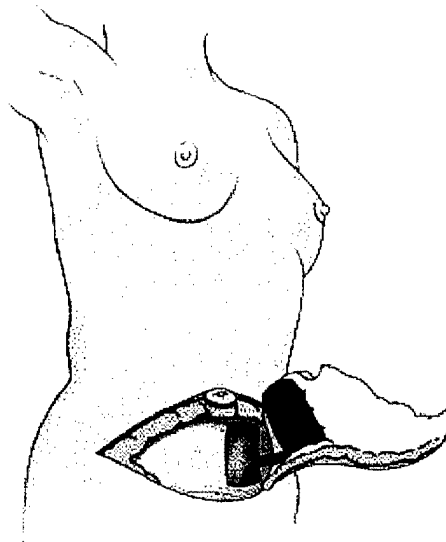
[Women considering breast reconstruction should not] be overly encouraged that their results would be entirely positive, nor overly discouraged that they would have any negative results, but to really trust themselves in making this decision, because it really is such a personal decision. You really have to judge your own tolerance for pain, your own motivation. I would not urge this surgery for someone who is looking for perfection or a denial of the disease. That's not what this is about. It's really an expression of hope and an optimism about the future."

scarred and deformed site that used to be my breast is gone. I feel whole again. I like my new body and flat belly and am back to doing everything I ever did. My two breasts don't match exactly, but that's O.K. with me. At this time I don't think I'll go back to have color tattooed on the areola. Would I do it again? Yes, but I think once around is enough."

2. Free TRAM

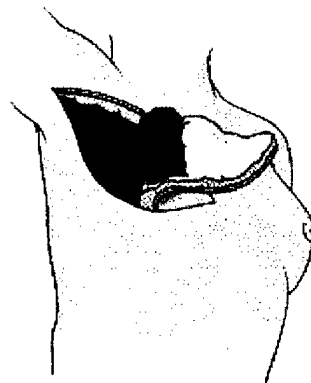
The "free flap" (microsurgical) TRAM commonly uses the same tissue as the "tunneling" method described above.

The main difference in the free TRAM reconstruction is that the tissue, rather than remaining attached, is completely removed from the body.

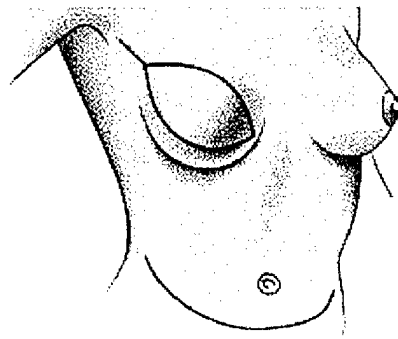


Following its removal from the abdomen, the tissue is transferred to the mastectomy site. This requires that the artery and vein which supply blood to the flap tissue to be identified and cut as well.

When the tissue is brought up to the mastectomy site, the flap's artery and vein are reattached to blood vessels in the underarm using microsurgical procedures.



Some surgeons prefer



Breast scar may vary in appearance

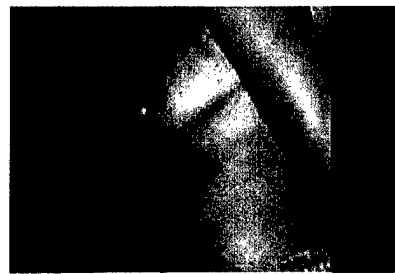
the "free flap" method to the "tunneling" method because they may be better able to sculpt the tissue to the shape of a normal breast (and thus to match the other breast). The main concern about the

free TRAM procedure is that the survival of the entire reconstruction depends upon the newly attached blood vessels to the flap tissue. If these fail, then the reconstructed breast can be lost.

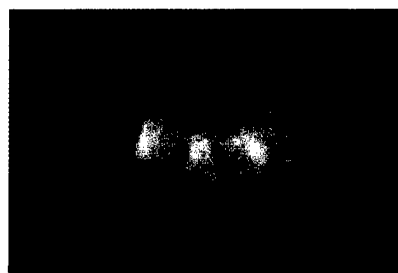
Finished Free TRAM Flap Reconstructions:



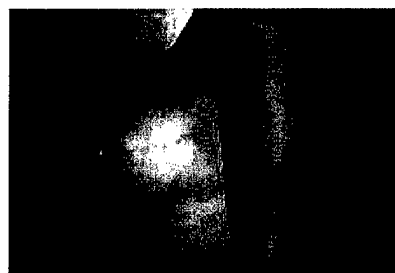
Free TRAM, Front View
(with nipple reconstruction)



Free TRAM, Side View
(with nipple reconstruction)

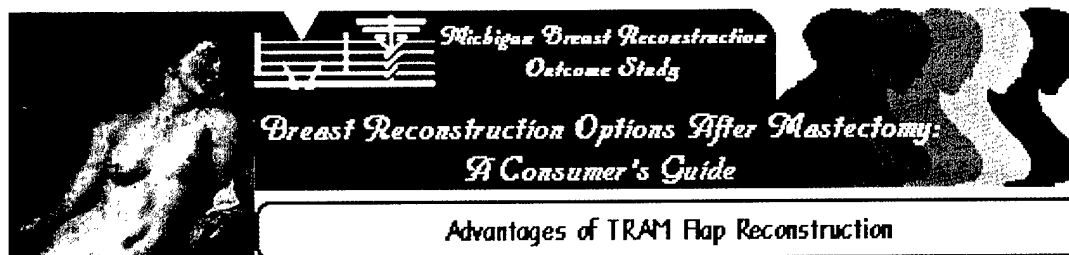


Free TRAM, Front View
(with nipple reconstruction)



Free TRAM, Side View
(with nipple reconstruction)

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The new reconstructed breast is made of natural tissue.

This procedure requires less foreign material to be put into your body than is put in with an implant: prosthetic mesh may be used in closing the abdominal wall, but no foreign material is incorporated into the breast itself. This eliminates the possibility of having to get an implant replaced in the future. The use of your own tissue also allows the doctors to sculpt the tissue to match your other breast to the best of their ability. Natural tissue reconstruction is important if you gain or lose weight. Since your new breast is your own tissue, it will change as the rest of your body changes. However, it is important to remember that it may not change exactly like your other breast.

The procedure only takes one step.

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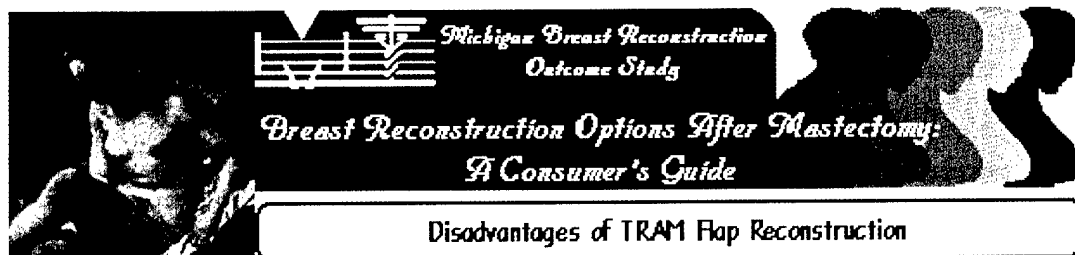
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Unlike the implant procedure, which usually requires two operations, the construction of the 'breast mound' with natural tissue usually requires only one step. This step, depending on whether you choose immediate or delayed reconstruction, can be done at the same time as the mastectomy, or later. At first, the breast will be slightly larger than planned, but after the swelling goes down it will shrink a bit. Some patients may have additional shaping done later. The construction of the nipple and areola have to be done at a later date, regardless of which type of procedure you choose.

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This is *major* surgery.

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Many women have said that this procedure will take a major toll on your body and your lifestyle during your recovery period. The operation itself may take eight hours or more, and the hospital stay afterwards can be up to five days. When you return home from the hospital, your life probably won't be back to normal. Generally, women who go through this procedure may need up to six to eight weeks of absence from work. During this time, you are restricted to how much you can lift (no more than 5 pounds), how active you can be, and even how much you can travel (no driving for one month). Depending on your lifestyle, this may severely impact your day to day activities. Some women who have gone through this procedure have experienced substantial pain, often lasting well after the surgery is completed. Some say that full recovery (a complete return to normal) can be as long as six months to one year after surgery. However, for other women, the lifestyle disruptions may be less severe. Recovery from this surgery will be determined by how well your body recovers from any challenge it faces.

The procedure may cause changes in body function after recovery.

With a TRAM flap, some women may find their abdominal muscles to be weaker, even after full recovery from the operation. This could affect your power to sit up. This change may be especially hard for you if you are older or especially athletic. For women of childbearing age, some doctors do not recommend pregnancies after the TRAM surgery. The weakened abdominal muscles may also put some additional strain on your back.

The surgery leaves an additional scar and may cause changes in body appearance.

After the surgery and recovery period, some women notice that the contours of their bodies are different. In the case of a "tunneled" TRAM, some women have a slight visible

bulge where the abdominal muscle turns upward. TRAM reconstruction also leaves another scar on the body. The scar may run from hip to hip, just above the pubic bone. However, this scar can be hidden by many forms of swim suits.

It is difficult to predict exactly what the new breast will look like.

With TRAM reconstruction, the surgeon must mold and sculpt tissue into a breast shape. Therefore, depending on the surgeon's technique and the quantity and quality of the tissue, there is variation in what the reconstructed breast will eventually look like. This makes it somewhat difficult to predict the final result of the surgery.

The procedure may cause complications.

In some rare cases, women who have natural tissue breast reconstruction experience partial or complete loss of the newly constructed breast. About six women in 100 lose part of the new breast; less than one in 100 lose the entire breast. This is usually due to circulation problems that starve the tissue of needed nutrients.

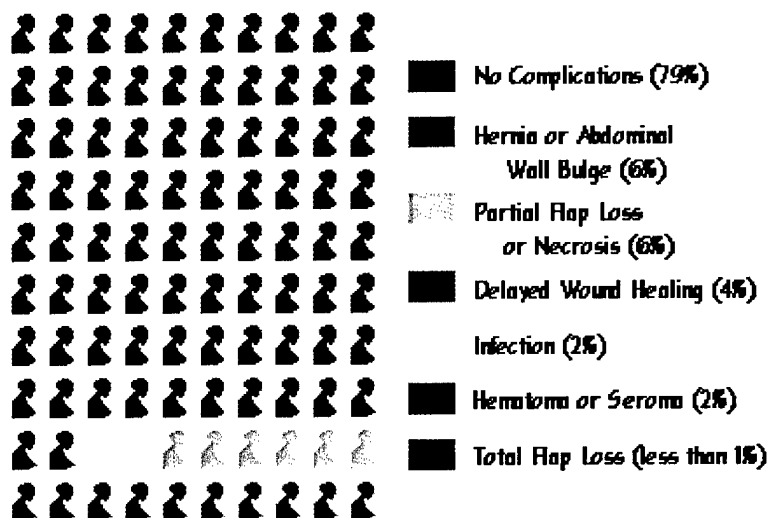
Partial flap loss can occur within the first 10 days after surgery if some of the TRAM tissue dies. In such a case, the dead tissue may be surgically removed and the edges of live skin brought together again, or the area may be treated with dressing changes. Partial flap loss may also happen several months after surgery, when clumps of dead fat inside the breast flap harden to form lumps ("necrosis"). These lumps are usually removed by surgery, so that they will not be mistaken for cancer.

In some cases, loss of flap circulation soon after surgery can be treated with additional surgery to adjust the tissue and restore circulation. However, the flap must be removed in cases that can't be helped by additional surgeries. If another donor site is available, these women may be able to have another reconstruction using natural tissue. However, the donor site that was used the first time cannot be used again.

A few women who have TRAMs (about six in 100) experience abdominal wall bulges or hernias due to the changes in the abdominal muscle structure. The abdominal wall is weakened during TRAM reconstruction. Therefore, tissue beneath the remaining muscles may press against them, causing an abdominal wall bulge, or protrude

through them, causing a hernia. Treatment of a hernia involves additional surgery, which requires additional hospital stays and lifestyle disruptions.

About four women in 100 take longer than normal to heal after the operation. In very rare cases (two out of 100) a woman will have some bleeding (called a "hematoma") or fluid collection (called a "seroma") under the breast skin after surgery. Finally, about two women out of 100 develop infections in the area of the incision soon after surgery.



Complication rates adapted from Wilkins EG et al,
Journal of the American Cancer Society 1995; 180(2):177.

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No Complications (79%)

Hernia or Abdominal Wall Bulge (6%)

Partial Flap Loss or Necrosis (6%)

Delayed Wound Healing (4%)

Infection (2%)

Hematoma or Seroma (2%)

Total Flap Loss (less than 1%)

Complication rates adapted from Wilkins EG et al,
Journal of the American Cancer Society 1995; 180(2):177.

TRAM COMPLICATIONS:

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Hernia or Abdominal Wall Bulge

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Partial Flap Loss or Necrosis

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The abdominal wall is weakened during TRAM reconstruction. Therefore, tissue beneath the remaining muscles may press against the muscles, causing an abdominal wall bulge, or protrude through them, causing a hernia. These may need to be corrected by surgery.

Some of the TRAM flap may be lost after surgery. Some of the flap tissue may die ("partial flap loss," which usually occurs within 10 days after surgery) or lumps of dead fat in the breast may become hardened and need to be removed ("necrosis," which may happen several months after surgery). These may need to be corrected by surgery.

Delayed Wound Healing

The surgical incisions may take longer than normal to heal.

Infection

The surgical incisions may become infected soon after the surgery.

Hematoma or Seroma

A pocket of blood ("hematoma") or blister fluid ("seroma") may form under the breast skin soon after the surgery.

Total Flap Loss

In very rare cases (less than 1%), the entire TRAM flap may die and be lost. This will need to be corrected by surgery.

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Latissimus Dorsi Flap Reconstruction

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One of the available donor site options for breast reconstruction is the latissimus dorsi muscle, or the muscle next to your shoulder blade. By "tunneling," the flap tissue muscle and skin covering it ("skin island") are brought around from the back of the body to the front and are placed at the mastectomy site. Because there may not be enough "filler" in this area of the back to match the size of the other breast, this procedure may also require the placement of an implant.

Generally, this donor site is used in cases where the abdominal tissue is not suitable for use in reconstruction. This donor site may also be used in cases where the abdominal tissue was previously used for reconstruction, but the newly reconstructed breast was partially or completely lost due to complications. Some plastic surgeons may recommend latissimus dorsi reconstruction even if the TRAM donor site is available.

Many of the same concerns exist for this surgery as for the TRAM surgery. A hospital stay of three to five days may be required. The same general recovery time applies for this procedure as the TRAM procedure.

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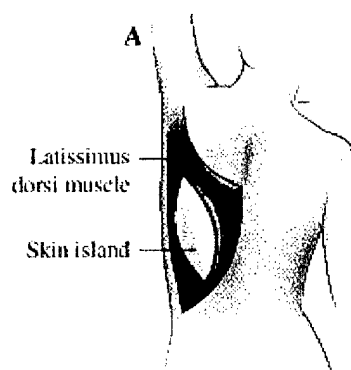
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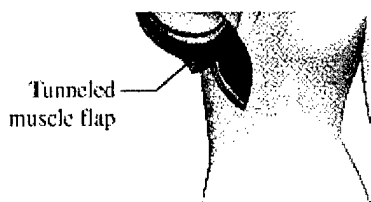
How is Latissimus Dorsi Flap Reconstruction Done?

A flap of skin and muscle is separated from the shoulder blade area.



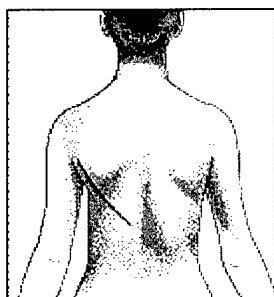
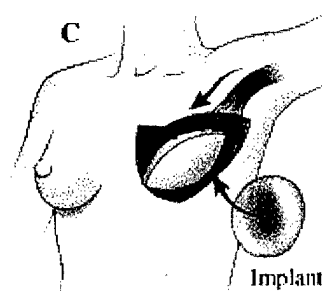
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The flap is tunneled from the back of the body to the mastectomy site.

The flap is shaped into a reconstructed breast. An implant is placed under the chest muscle to give the breast fullness.



Size and location of scar varies

The donor site on the back is stitched closed.

Advantages of Reconstruction Using the Latissimus Dorsi Muscle:

- The tissue area and the blood vessels involved are large and dependable, making it likely that the operation will be successful.

Disadvantages of Reconstruction Using the Latissimus Dorsi Muscle:

- You may need to have an implant placed under the flap to create a large enough breast.
- The surgery may leave a sizeable scar in a potentially prominent area of the back. This scar may be particularly easy to see on women wearing swimsuits and summer clothes.

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In some instances, natural tissue reconstruction is performed using tissues from other areas of the body. These additional donor sites include the shoulder blade area (latissimus dorsi muscle flap), the outer thigh, the inner thigh, and the buttocks (superior and inferior gluteal muscle flaps). In the hands of most plastic surgeons, these sites are used less often than TRAM flaps. With the exception of latissimus dorsi reconstruction, these additional flaps are all performed as free (microsurgical) procedures. As with the free TRAM described earlier, these free flap procedures involve completely detaching the tissue from the donor site and re-establishing the flap's circulation by reconnection of flap blood vessels to a local artery and vein at the breast site. By contrast, reconstruction with the latissimus dorsi muscle from the shoulder blade area involves tunneling the tissue to the front side of the chest for use in the reconstruction of a new breast.

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Implants vs. "Tunneled" and "Free" TRAMs: And the Study Says...

The Michigan Breast Reconstruction Outcome Study (MBROS) surveyed 212 breast reconstruction patients one year after their surgeries to determine how satisfied they were with the results. 23% of the women chose implants; 48% chose "tunneled" TRAMs, and 29% chose free TRAMs (1-2).

General Patient Satisfaction

Women who chose TRAMs of either type were 2.17 times as likely as women who chose implants to be satisfied in general with their breast reconstructions ($p < 0.033$, which means that there is a 3.3% probability that these results are due to chance). 77.8% of TRAM patients (both "tunneled" and free TRAMs) were "very satisfied" with their results in general, compared with 61.2% of implant patients ($p < 0.021$). Patients who were physically active before the surgery were 1.68 times more likely to be satisfied with their surgeries than those who were not ($p < 0.034$). This greater satisfaction among women who are active may be explained by the fact that people who exercise regularly are likely to have better health status and better emotional health, which means that they are likely to have fewer surgical complications and better outcomes. The age of the patient made no difference in how satisfied she felt with the results of her surgery.

Patient Satisfaction With Appearance of Reconstructed Breasts

Women who chose TRAMs of either type were also 4.7 times as likely as women who chose implants to be satisfied with the appearance of their reconstructed breasts ($p < 0.0001$, which means that there is a one in 10,000 probability that these results are due to chance). 75.2% of TRAM patients reported being "very satisfied" with the aesthetic results of their surgery, compared with 40.4% of implant patients ($p < 0.001$). Those who chose "tunneled" TRAMs were twice as likely as those who chose free TRAMs ($p < 0.047$) and 6.67 times as likely as those who chose implants ($p < 0.01$) to be satisfied with the

looks of their new breasts. The physical activity level and age of the patient had no effect on their satisfaction with the aesthetic results of their surgery.

Objective Measurements of Symmetry of Reconstructed vs. Natural Breasts

The women's¹ assessments of the appearance of their reconstructed breasts are confirmed by objective measurements. Another MBROS study (3) examined computer-generated measurements of photographs of the breasts of women who had undergone "tunneled" TRAMs, free TRAMs, and implants, in order to determine the degree of symmetry achieved using the different reconstructive techniques. This study found that TRAMs yielded more symmetrical results than implants in all four dimensions examined. (The results in three out of four of these dimensions were statistically significant.) Furthermore, "tunneled" TRAMs produced more symmetrical results in all dimensions than did free TRAMs. Overall, there was an average difference in measured dimensions between the natural and the reconstructed breast of 3.15% for "tunneled" TRAMs, compared to 4.21% for free TRAMs and 4.91% for implants ($p < 0.028$).

Effects on Physical Functioning

In another MBROS study (4), 71 women were tested both before their surgeries and one year afterwards to determine the effects of different breast reconstruction techniques on physical functioning. 23% of the women had implants, 37% had "tunneled" TRAMs, and 40% had free TRAMs. One year after their operations, the women who had TRAMs, whether "tunneled" or "free," had less sit-up power than those who had implant reconstructions ($p < 0.001$). There were no significant differences between procedures in other physical tests, such as lifting the arm from the shoulder or bending deeply at the waist. Moreover, based on questionnaire results one year after surgery, regardless of the type of breast reconstruction, the women reported no differences in their ability to perform normal daily activities. Thus, although both types of TRAMs interfere somewhat with abdominal muscle function, there appears to be no effect on the performance of daily activities.

1. Alderman AK, Wilkins EG, Lowery JC, Kim M
Determinants of patient satisfaction in post-mastectomy breast reconstruction. Submitted to Plastic and Reconstruction Surgery, July 1999.
2. Reynolds JR, Wilkins EG, Lowery JC, Kuzon WM, Goldfarb SL. Objective assessment of aesthetic outcomes in breast reconstruction. To be presented to the American

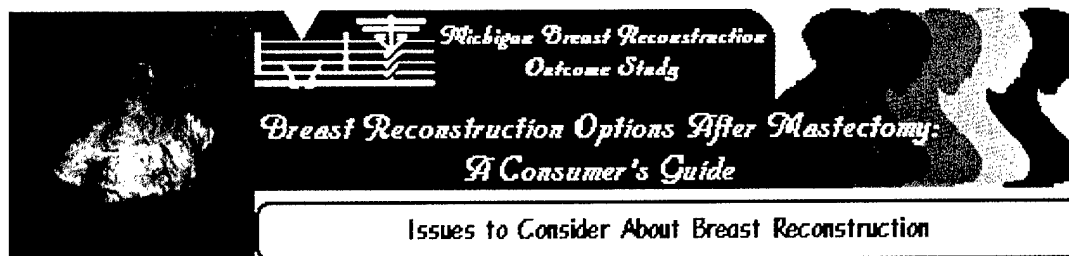
Society of Plastic and Reconstructive Surgeons, October 1999.

3. Wilkins EG, Lowery JC, Kuzon WM, Perkins A.
Functional outcomes in postmastectomy breast
reconstruction: preliminary results of the Michigan Breast
Reconstruction Outcome Study. Surgical Forum 1997; 48:
609-612.

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If you are interested in breast reconstruction, some practical questions you may want to think about include:

- Should my reconstruction be immediate or delayed?
- Who will do my reconstruction?
- Who will pay for my reconstruction?
- Should I have mammograms after my reconstruction?

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You've talked with your doctor and decided to have your breast reconstructed. Should you have it done at the same time as the mastectomy or wait until later? All types of breast reconstruction can be done either at the same time the cancerous breast is removed or later--even years later. Your doctor may suggest that one option is better for you, depending on your body and your health.

Advantages of Immediate Breast Reconstruction:

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- You wake up after cancer surgery with a new breast, or the beginnings of a new breast, already in place.
- Most women feel better about seeing the results of the cancer surgery for the first time if they have had immediate reconstruction.
- It saves time and effort, since you have two surgeries at the same time.

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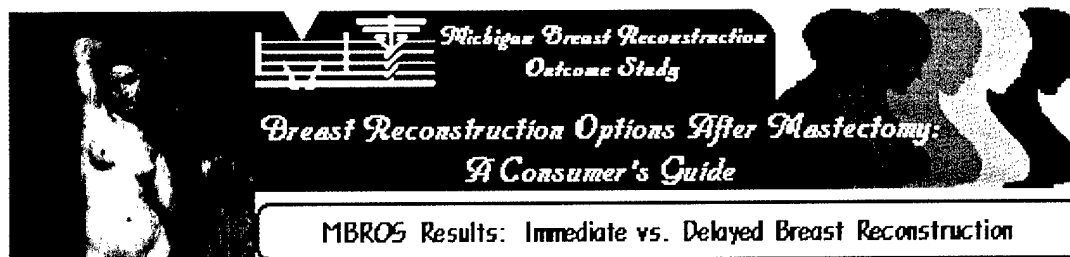
Disadvantages of Immediate Breast Reconstruction:

- You must bear the strain and the possible problems of two surgeries at once.
- There is no chance to adjust to the loss of the old breast before you get the new one.
- You must deal emotionally with cancer and with reconstruction at the same time. Some women prefer to have the cancer treated first and to think about reconstruction afterwards.

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Immediate vs. Delayed Breast Reconstruction: And the Study Says...

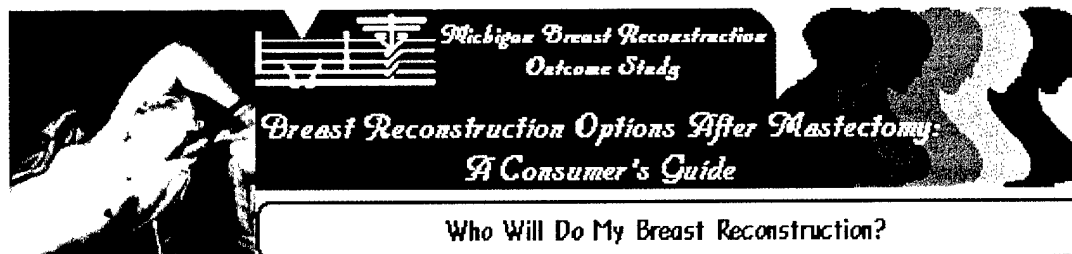
The Michigan Breast Reconstruction Outcome Study (MBROS) surveyed 250 breast reconstruction patients before surgery and one year after surgery. Two thirds (161) of the patients chose immediate reconstruction, while one-third (89) chose delayed reconstruction. The study found that there were no differences between immediate and delayed reconstruction in the amount of improvement patients observed in general mental health, emotional well-being, or ability to perform normal daily activities (1). Not surprisingly, since they started with no breast, those who chose delayed reconstruction experienced the greatest improvements in their feelings about the way they looked after reconstruction. Of the women who had delayed reconstruction, those who chose implants had higher energy levels than those who chose natural tissue reconstruction. However, they also reported being less satisfied with the way the results looked. There were no differences in energy level or in satisfaction with the results among those who had immediate breast reconstruction, regardless of which procedure they chose.

1. Cederna PS, Lowery JC, Davis JA, Kim HM, Roth RS, Goldfarb S, Wilkins EG. A prospective analysis of the psychosocial outcomes of postmastectomy breast reconstruction: preliminary results from the Michigan Breast Reconstruction Outcome Study. Unpublished manuscript, 1999.

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The breast reconstruction is done by a plastic surgeon. While your surgical oncologist is responsible for your mastectomy and treating your cancer, your plastic surgeon focuses on reconstructing your breast. If you decide to have immediate reconstruction, the plastic surgeon will need to coordinate with your oncologist to plan your surgery.

Plastic surgeons are first trained as medical doctors. After medical school, they receive five to eight years of specialized training in plastic surgery. Plastic surgeons perform many complicated surgeries. They re-attach hands after accidents, reconstruct body parts for burn patients, and repair wounds. However, it is always good to ask if your surgeon has experience in breast reconstruction. You should make sure that your doctor is a "board certified" or "board eligible" plastic surgeon. Also, your surgeon should be willing to talk with you about both cosmetic and surgical issues. Remember that the surgeon works for you: you can choose to stop reconstruction at any point, from choosing no reconstruction to declining nipple reconstruction and tattooing.

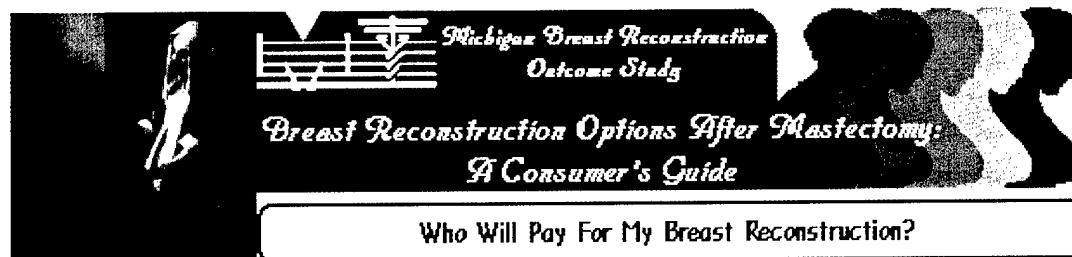
A PATIENT SAYS. . .

"The choice of surgeon was probably the second most critical factor for me [after deciding to do the surgery and getting information about it]. And finding someone I felt very optimistic with and encouraged by and felt very much part of a team. So that was the difference in talking with someone who's only done a few of these surgeries and then talking with someone like Dr. _____ who has done so many of them, really made me feel far more comfortable."

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Insurance companies and managed care organizations are now required to pay for breast reconstruction for women who have had a mastectomy. Health care plans are also required to pay for surgery to make the opposite natural breast match the reconstructed breast. The Women's Health and Cancer Rights Act of 1997, which ensures these rights, states that:

"A group health plan, and a health insurance issuer providing health insurance coverage in connection with a group health plan, that provides medical and surgical benefits with respect to a mastectomy shall ensure that, in a case in which a mastectomy patient elects breast reconstruction, coverage is provided for--

1. *all stages of reconstruction of the breast on which the mastectomy has been performed; and*
2. *surgery and reconstruction of the other breast to produce a symmetrical appearance;*

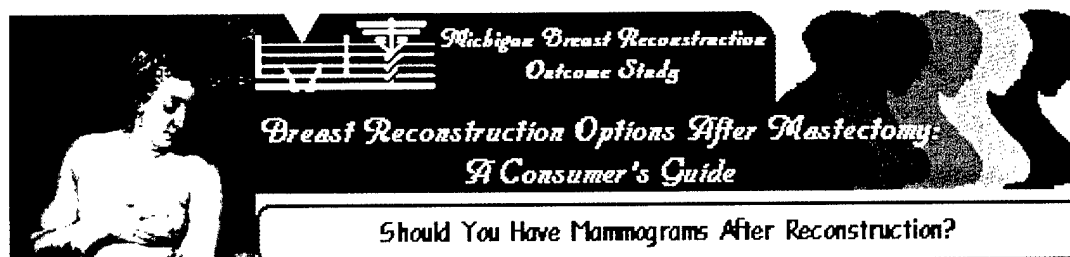
in the manner determined by the attending physician and the patient to be appropriate, and consistent with any fee schedule contained in the plan."

This law is also observed by Medicare and Medicaid. However, you should still check with your insurance company ahead of time - most companies require that you obtain authorization in advance about any surgery that is not an emergency. Also, not all insurance companies cover nipple tattooing, so ask about this procedure if you think you would like to have it done. If you do not have insurance, you should talk with your doctor about the cost of the breast reconstruction surgery, office visits, and potential additional costs due to implant or TRAM complications.

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If You Had an Implant:

If you have had an implant, mammograms are usually not recommended for the reconstructed breast. Most physicians prefer to screen for local recurrence of cancer with physical examinations of the breast.

Do self breast exams on both breasts once a month and visit your doctor as recommended for a checkup. Continue to have mammograms done on the natural breast as recommended by the American Cancer Society or your physician. (American Cancer Society guidelines are listed below for your convenience.)

If You Had Natural Tissue Reconstruction:

Increasingly, providers are recommending that TRAM reconstructions be periodically screened with mammograms. Try to find a mammography facility that is experienced in doing mammograms on reconstructed breasts. In addition, most physicians also rely on physical examinations of the breast to detect cancer recurrences. Do self-exams on both breasts once a month and visit your doctor as recommended for a checkup. Continue to have mammograms done on both breasts as recommended by the American Cancer Society or your physician. (American Cancer Society guidelines are listed below for your convenience.)

For more information, see the MBROS Study Results on Mammography After TRAMs ("Tramograms").

American Cancer Society Mammography Screening Guidelines			
If You Are:	Have a Mammogram:	Have a Doctor Examine Your Breasts:	Do Self Breast Exams:
	(none)	Once	

20-39	(none recommended)	every 3 years	Monthly
40-49	Once every 2 years	Once a year	Monthly
50 or over	Once a year	Once a year	Monthly

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Mammography for TRAMs ("Tramograms"): And the Study Says...

The Michigan Breast Reconstruction Outcome Study (MBROS) reports that, under certain conditions, recurrence of cancer in TRAM patients, although rare, may be frequent enough to warrant routine mammography (1). The study reports four case studies of TRAM patients who experienced local recurrences of cancer or new cancers in their reconstructed breasts. The patients shared the following characteristics:

- They had originally had extensive, multifocal ductal carcinoma in situ (i.e., well developed cancer of the milk ducts that had spread to several places in the breast).
- They had had skin-sparing mastectomies with surgical incisions less than 1 millimeter from the edge of the cancerous area.
- They had had immediate TRAM flap reconstruction.

Three of the cases were detected on physical examination by a physician. One was detected by a mammogram. All recurrences occurred within five years of the mastectomy and TRAM flap reconstruction.

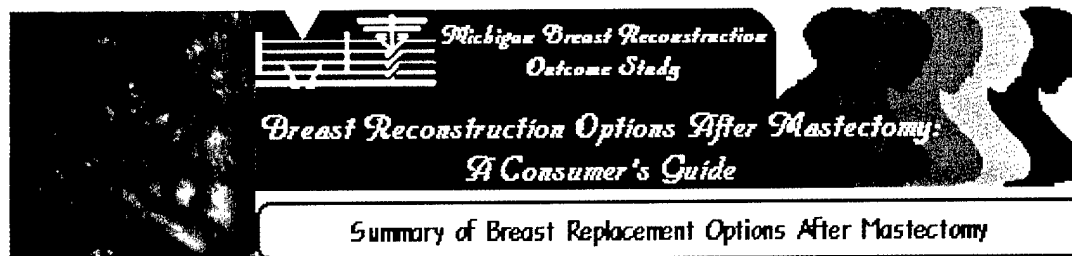
Mammography of reconstructed breasts is controversial, as recurrence of cancer in reconstructed breasts is very rare. A 1997 review of 1707 reconstruction patients reports recurrence of cancer in only 1.4% of the cases (2). Moreover, benign irregularities in the flap tissue, such as fat necrosis, oil cysts, and scar tissue, can easily be mistaken for cancer in a mammogram. In some cases, recurrence of cancer may be detected earlier with a mammogram than with physical examination. However, it has not been proven that recurrences detected by mammogram can be treated more successfully than those detected by physical exam.

On the other hand, if the recurrences can be treated earlier, it will minimize the damage done by the cancer and may make it possible to save the TRAM flap.

1. Salas AP, Helvie MA, Wilkins EG, Oberman HA, Possert PW, Yahanda AM, Chang AE. Is mammography useful in screening for local recurrences in patients with TRAM flap reconstruction after mastectomy for multifocal DCIS? *Annals of Surgical Oncology* 1998; 5(5):456-463.
2. Delaney G, Ung O, Cahill S, Bilous M, Boyages J. Ductal carcinoma in situ. Part 2: Treatment. *Australia and New Zealand Journal of Surgery* 1997; 67:157-165.

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	PROS- THESIS	IMPLANT (NO TISSUE EXPAN- SION)	TISSUE EXPANDER FOLLOWED BY IMPLANT	NATURAL TISSUE: TRAM (Abdom- inal Flap)	NATURAL TISSUE: LATISSI- MUS DORSI (Back Flap)
Who is a Candidate?	All women.	Very small- breasted women.	Most women.	Most women.	Most women.
Timing	A lightweight style is best for the initial recovery period. After mastectomy scar heals, you can switch to a more lifelike silicone model.	May be immediate or delayed.	May be immediate or delayed.	May be immediate or delayed.	May be immediate or delayed.
Length of Recovery	None.	3-4 weeks may be required before it is possible to return to work or perform	3-4 weeks may be required before it is possible to return to work or perform	Most women can resume normal activities after six to eight weeks. During this	Most women can return to work and resume other normal activities after 4-6 weeks.

		strenuous activities.	strenuous activities.	period, lifting objects heavier than five pounds is not permitted.	
Scarring	Scars from mastectomy only.	None or very little additional scarring, since mastectomy incision is usually reopened to insert implant.	None or very little additional scarring, since mastectomy incision is usually reopened to insert implant.	Scarring at the donor site, on the abdomen. For TRAM, this is a scar running from hip to hip. Mastectomy site scar on chest.	Scarring at donor site, on the back. Mastectomy site scar on chest.
Drains	Drains from mastectomy only.	Wear drains for 3 days to 2 weeks. One week is about average.	Wear drains for 3 days to 2 weeks. One week is about average.	Wear drains for three days to as long as three weeks. One week is about average.	Wear drains for three days to as long as three weeks. One week is about average.
Hospital Stay	Hospital stay for mastectomy only (outpatient to 2 days).	1-2 days if immediate; none (outpatient) to 1 day if delayed.	1-2 days if immediate; none (outpatient) to 1 day if delayed.	3-5 days.	2-4 days.
Follow-	None.	Additional	An	Additional	If an

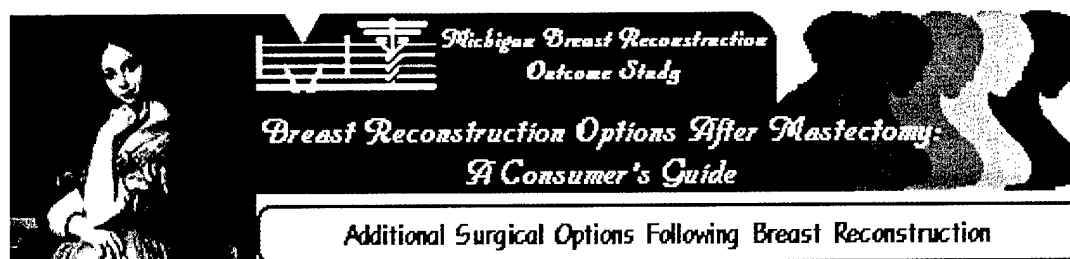
Up Surgeries		surgeries may be necessary to remove or repair the implant if it leaks, hardens, or becomes infected.	additional surgery will be necessary to remove the tissue expander and insert an implant. Further additional surgeries may be necessary to remove or repair the implant if it leaks, hardens, or becomes infected. Surgeries on the opposite breast may be required to achieve symmetry.	surgeries may be required for additional contouring or in case of complications, such as hernia. Surgeries on the opposite breast may be required to achieve symmetry.	implant is used with the back flap, additional surgeries may be necessary to remove or repair the implant (see "Implant" columns).
Possible Complications and Concerns	Adapting swimsuits and lingerie to hold the prosthesis. Feeling self-conscious in revealing clothes. Sweating	Implant can leak, harden, or become infected. This will lead to more surgery to remove or replace the implant. If a	Tissue expander can leak or become infected, which may lead to more surgery to remove or replace the tissue expander.	Hernia; potential loss of abdominal wall strength; changes in overall body appearance, Potential loss of reconstructed breast.	Potential loss of reconstructed breast. Implant complications if an implant was used (see "Implant" columns).

	underneath the prosthesis. Not being able to scratch an itch.	silicone implant was used, more lengthy and complicated surgery may be needed to remove any silicone.	Implant can leak, harden, or become infected. This will lead to more surgery to remove or replace the implant. If a silicone implant was used, more lengthy and complicated surgery may be needed to remove any silicone that may have spread throughout the body.	
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Many women choose to have additional surgeries after breast reconstruction to make their breasts look as natural and symmetrical as possible.

Nipple reconstruction may be done on the reconstructed breast mound to make the it look more natural and "complete."

Additional surgeries may be done to make the opposite, natural breast look as much like the reconstructed breast as possible:

- [Breast lift](#)
- [Breast reduction](#)
- [Breast augmentation](#)

(See the [Options Summary](#) table for a listing of the major features of each of these surgeries.)

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Nipple and areola (the dark circle around the nipple) reconstruction is completely optional. Some women want only the shape of the breast to fill a bra, and decide they don't need a nipple. Another option is to apply removable nipples that stick on with adhesive. These rubbery tips are shaped like a semi-erect nipple and the color and texture are quite lifelike.

How is Nipple Reconstruction Done?

If you choose to surgically reconstruct the nipple, there are several options. One common option is to use the skin of your reconstructed breast. The surgeon can take a small flap of skin from the breast, and "cone" it into a new nipple. Because the nerves aren't connected in the reconstructed breast, most women do not feel much pain with this surgery.

Options to reconstruct the areola involve taking skin from a different part of the body and sewing it to the new nipple on the reconstructed breast. The surgeon can take an oval of skin from the outer edge of your mastectomy scar or from the edge of the TRAM donor scar on your abdomen (if you have this kind of breast reconstruction). The advantage of using this skin is that you won't have any new scars. The surgeon can also take skin from the inside of your thigh or from just below your hip bone. You may be sore for up to two weeks at the place from which the skin was taken. However, most women have very little discomfort at the site of the reconstructed nipple. Another option is to reconstruct the nipple as described above and have the skin around it tattooed to a darker color to make an areola.

In all procedures, you will not have much or any feeling in the new nipple when it is touched. These surgeries can be done on an outpatient basis in under two hours, with local or general anesthesia. Most doctors will ask you to wait a week after the surgery before driving or working.

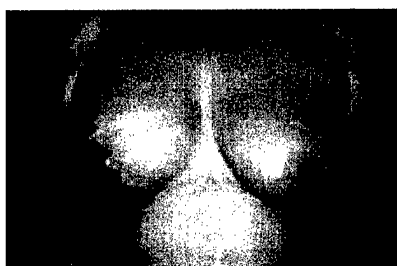
After you have healed, you can have the new nipple and areola tattooed to match the color of your other nipple. Often it takes two or three sessions to color the whole area evenly. Tattooing takes about an hour and can be done in the doctor's office. You can usually go back to work the same day. Most women can hardly feel the tattooing being done. However, your doctor may

use a local anesthetic just in case.

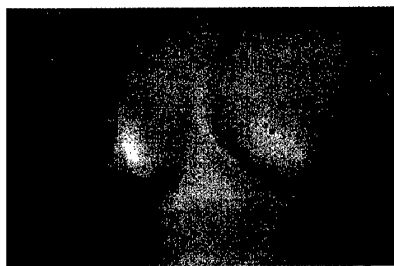
When Can I Have Nipple Reconstruction?

Most plastic surgeons do not schedule nipple reconstruction until at least three months after breast reconstruction. You want to allow time for the swelling from the surgery to go down and for the breast to "settle." This allows the surgeon to place the nipple so that it matches the position of the nipple on the other breast. In some circumstances, the plastic surgeon can perform nipple reconstruction at the same time as reconstruction of the breast itself. You may want to discuss this option with your provider.

Finished Nipple Reconstructions:



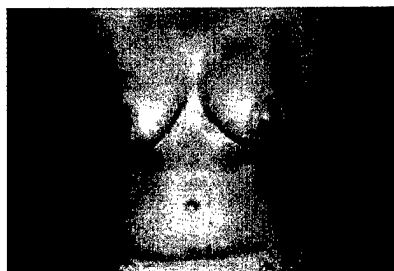
Implant with Nipple Reconstruction



Pedicle TRAM with Nipple Reconstruction



Free TRAM with Nipple Reconstruction



Free TRAM with Nipple Reconstruction

Advantages of Nipple Reconstruction:

- Your reconstructed breast will match your natural breast more closely.
- You can go bra-less and have the shape of the nipple on both sides.

Disadvantages of Nipple Reconstruction:

- It is usually an additional surgery and requires another recovery period.
- If the skin is taken from a place where there is no scar, you'll have a new scar at the donor site.

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While reconstructive surgery can usually give you the volume to fill a bra evenly, it may be difficult to create the same shape on both sides. The reconstructed breast may not droop like the natural breast. However, the surgeon can do a breast lift, or mastopexy, to make the natural breast look more youthful so that it better matches the reconstructed breast.

How is Breast Lift Done?

In breast lift, the surgeon cuts out a section of skin from the lower part of the breast. This skin is removed, and the nipple is moved upward. Skin that was previously above the nipple is drawn down and sewn together below the nipple. Because there is less skin, the breast is higher and firmer after surgery. The scars are usually around the areola, in a vertical line extending down from the nipple area, and along the lower fold of the breast.

This surgery takes from one to two hours, with either local or general anesthesia. It is usually done in a day-only visit to either a clinic or hospital. Many women return to work after a week, and resume their normal activities after two to three weeks.

After having a breast lift, you may lose some feeling in your nipple or breast for at least six weeks. This loss of feeling usually resolves as the swelling goes down after surgery, but in some women it can last as long as a year or even be permanent. Breast lift also leaves permanent scars. These can be lumpy and red for months following surgery, fading bit by bit until they are less noticeable. The scars can, however, be hidden under most bathing suits.

If you choose this procedure, be aware that gravity, aging, and weight changes will cause the breast to eventually sag again. However, this may happen in the reconstructed breast as well.

Advantages of Breast Lift:

- The lifted breast will more closely match the shape of your reconstructed breast.
- The lifted breast will be higher and firmer after surgery.

Disadvantages of Breast Lift:

- Breast lift is additional surgery.
- You will have permanent scars (although they can be covered by a bathing suit).
- There is a small possibility that you will permanently lose feeling in your nipple or breast.

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If your natural breast is large compared to your reconstructed breast, you may want to consider breast reduction. Breast reduction removes skin and fat from the breast.

How is Breast Reduction Done?

In breast reduction, the surgeon removes fat, glandular tissue, and skin from the lower part of the breast. The nipple is then moved upwards and the tissues closed to form a smaller breast. As in breast lift, the scars are usually around the areola, in a vertical line extending down from the nipple area, and along the lower fold of the breast.

The surgery usually takes from one to two hours but can take longer. It is done under general anesthesia, so you will be asleep through the operation. Breast reduction is usually done in the hospital and may require an overnight stay. Most women can return to work in three weeks and to all normal activities in three to four weeks.

After having breast reduction, as with breast lift, you may lose feeling in your nipple or breast for at least six weeks. This loss of feeling usually subsides gradually as the swelling goes down after surgery, but in some women it can last as long as a year or even be permanent. If the breast is especially large and hangs very low, the nipple and areola may have to be completely removed and resewn onto the breast higher up, in which case the nipple and areola will permanently lose all feeling.

Breast reduction, like breast lift, leaves permanent scars. These can be lumpy and red for months following surgery, fading bit by bit until they are less noticeable. In a few cases, if only fat needs to be removed, liposuction can be used, which leaves small scars. The scars can, however, be hidden under a bathing suit.

It may be six months to a year before the reduced breast settles into its final shape. If you are of an age to have children and are interested in breastfeeding, you should know that you may not be able to breastfeed with a reduced breast. The breast may also change size with hormonal changes, pregnancy, or weight changes. These shifts may not be a problem if you have had

natural tissue reconstruction on the other breast, as this breast may change in the same ways.

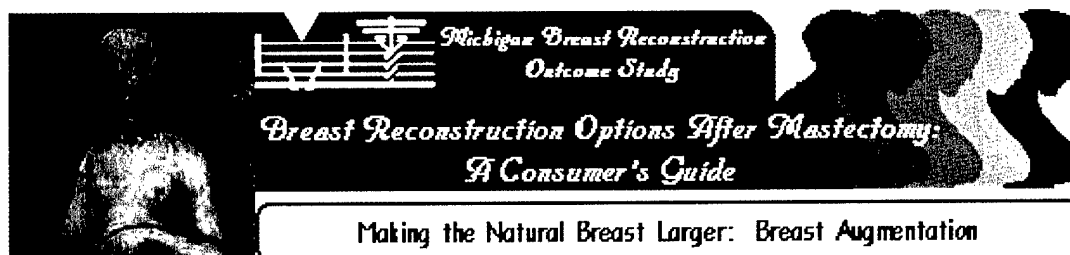
Advantages of Breast Reduction:

- The reduced breast will more closely match the shape of your reconstructed breast.
- The reduced breast will be smaller, which may relieve strain on your back and neck and reduce irritation in the breast crease if you have very large natural breasts.

Disadvantages of Breast Reduction:

- Breast reduction is additional surgery.
- You will have permanent scars (although they can be covered by a bathing suit).
- Breast reduction may leave your nipples and breast skin numb for six weeks to a year.
- In normal cases, there is a small possibility that you will permanently lose feeling in your nipple or breast. If your breast is particularly large and the nipple must be completely removed before being placed higher up, you are certain to permanently lose feeling in the nipple and areola.

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If your natural breast is small compared to your reconstructed breast, you may want to consider breast augmentation. In breast augmentation, the surgeon inserts an implant into your breast to make it larger. If your natural breast is small and droops, you may also be a good candidate for a breast lift. Your surgeon can tell you which procedure or combination of procedures is most appropriate for you.

How is Breast Augmentation Done?

In breast augmentation, the surgeon places an implant under your breast tissue to make it larger. The surgical incision may be made in the crease underneath the breast, around the areola, or in the armpit, depending on the surgeon, to make the scar as invisible as possible. The implant may go either under the breast tissue itself, or under the chest muscle behind the breast. The implant consists of a silicone "balloon" filled with silicone gel or saline.

This surgery takes about an hour, usually with general anesthesia. It is usually done either during a day-only visit to a clinic outside of the hospital or in the hospital with a stay of up to 24 hours. Most women can return to work after one to two weeks.

As the years go by, the implant may leak or rupture. This happens in approximately 10% of cases over the first 10 years. When this occurs, the implant must be removed or replaced. A capsule of scar tissue may also form around the implant. Scar tissue forms on the outside of all artificial implants when placed in the body. However, in approximately 5-10% of cases, too much scar tissue forms. The scar tissue may cause pain and discomfort and make the implant feel hard to the touch. Surgery may be necessary to break up or remove the scar tissue. It may also be necessary to remove or replace the implant. Capsules can form at any time from a few weeks to many years after the implant has been inserted.

If you undergo breast augmentation, you should realize that the placement of a breast implant in your augmented breast will affect, to some degree, your annual mammograms. If the implant is placed beneath the muscle layer, breast augmentation

will not likely have much effect on the quality of later mammograms. However, if you have an implant in your reconstructed breast and you would like to get a mammogram, you should look for centers that are experienced in screening women with implants.

Finished Breast Augmentations:



**Breast Augmentation
(opposite free TRAM)**

Advantages of Breast Augmentation:

- The augmented breast will more closely match the shape of your reconstructed breast.

Disadvantages of Breast Augmentation:

- Breast augmentation is additional surgery.
- The implant may develop complications over the years, such as leaks, ruptures, or excess scar tissue formation that may need to be corrected by extra surgery.
- You will need to get your mammograms done at a facility with expertise in treating implant patients.

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	Surgeries on the Reconstructed Breast	Surgeries on the Opposite Breast		
	NIPPLE RECONSTRUCTION	BREAST LIFT	BREAST REDUCTION	BREAST AUGMENTATION
Who is a Candidate?	Most women.	Most women.	Large-breasted women.	Small and medium-breasted women.
Timing	Usually at least three months after breast reconstruction.	May be done at the time of reconstruction or even years later.	May be done at the time of reconstruction or even years later.	May be done at the time of reconstruction or even years later.
Length of Recovery	Many women return to work in one week. Most women can resume normal activities after 1-2 weeks.	Many women return to work in 1-2 weeks. Most women can resume normal activities after 2-3 weeks.	Many women return to work in 3 weeks. Most women can resume normal activities after 3-4 weeks.	Many women return to work in 1-2 weeks. Most women can resume normal activities after 3-4 weeks.
Scarring	No new scarring if skin is taken from existing mastectomy or natural tissue reconstruction	Scarring around the areola, from the areola to the crease of the breast, and along the crease.	Scarring around the areola, from the areola to the crease of the breast, and along the crease.	Scarring at site of incision, which may be along the breast crease, at the areola, or in the

	scar. New scar on the thigh or hip if skin is taken from new areas.			armpit.
Drains	None.	May or may not have drains.	Wear drains for 1 - 7 days.	May or may not have drains.
Hospital Stay	None (outpatient).	From none to 1 day.	From none to 1 day.	From none to 1 day.
Follow-Up Surgeries	None. The nipple and areola may be tattooed in a doctor's office to color them if desired.	Surgery revision only in rare cases.	Surgery revision only in rare cases.	Additional surgeries may be necessary to remove or repair the implant if it leaks, hardens, or becomes infected.
Possible Complications and Concerns	Little or no feeling in the reconstructed nipple.	Initial numbness in nipples and breast skin for six weeks to a year. Occasionally the loss of feeling is permanent.	Initial numbness in nipples and breast skin for six weeks to a year. Occasionally the loss of feeling is permanent.	Implant can leak, harden, or become infected. This will lead to more surgery to remove or replace the implant. If a silicone implant was used, more lengthy and complicated surgery may be needed to remove any silicone.

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Recommended Reading

Bostwick, John. *Breast Reconstruction Following Mastectomy*. American Cancer Society. (A guide written for doctors.)

Also try these other [American Cancer Society](#) publications, written for patients:

- :Breast Reconstruction After Mastectomy:
- :Exercises After Breast Surgery:
- :Mastectomy: A Patient Guide:

Weiss, Marisa C. and Ellen T.F. Weiss. (1997) *Living Beyond Breast Cancer*. New York: Random House.

The nonprofit organization, also called Living Beyond Breast Cancer, is at:

- Tel: (610) 668-1320
- Fax: (610) 667-4789
- Internet: www.lbbsc.org

World Wide Web Resources

Information about Breast Reconstruction:

[American Society of Plastic and Reconstructive Surgeons:](#)
[Plastic Surgery Information Service](#)

[Center for Plastic Surgery](#)

[The Cleveland Clinic Foundation Guide to Breast Reconstruction](#)

[Department of Defense Breast Cancer Decision Guide for](#)

Military and Civilian Families

Memorial Sloan-Kettering Cancer Center

University of Iowa Department of Plastic Surgery Breast Reconstruction Page

Personal Testimonies from Breast Cancer Patients

Who Have Had Breast Reconstruction

One Woman's Story of Breast Cancer and Reconstruction (Nancy Delaney)

Patricia Murray

Olivia Newton-John

Other survivors

Useful Phone Numbers

American Cancer Society, 1-800-ACS-2345

National Cancer Institute, 1-800-4-CANCER

American Society of Plastic and Reconstructive Surgeons, 1-800-635-0635

Food and Drug Administration Breast Implant Information Line, 1-800-532-4440 (Ask for the updated Breast Implant Information Package)

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The Michigan Breast Reconstruction Outcome Study (MBROS) is a six-year study of multiple aspects of breast reconstruction outcomes. The study began in August of 1994 and will continue through June of 2000. During the lifetime of the study, MBROS has assessed a total of 397 actively participating patients from 11 medical centers in the U.S. and Canada. Patients are followed for two years from the date of their breast reconstruction surgeries to determine long-term outcomes of breast reconstruction. MBROS is supported by a grant from the Department of Defense, United States Army Medical Research and Material Command, DAMD 17-94-J-4044.

To date, studies have been completed on the following topics:

- Psychosocial outcomes of breast reconstruction.
- Psychosocial outcomes of breast reconstruction by timing of reconstruction (immediate vs. delayed).
- Psychosocial outcomes of breast reconstruction by procedure type (implants vs. pedicle TRAMs vs. free TRAMs).
- General patient satisfaction by procedure type (implants vs. pedicle TRAMs vs. free TRAMs).
- Patient satisfaction with aesthetic results by procedure type (implants vs. pedicle TRAMs vs. free TRAMs).
- Objective, computerized assessments of symmetry of breast reconstruction results by procedure type (implants vs. pedicle TRAMs vs. free TRAMs).
- Physical functioning one year after surgery by procedure type (implants vs. pedicle TRAMs vs. free TRAMs).
- Mammography after TRAM flap reconstruction.

Participating medical centers include:*Michigan:*

- University of Michigan Hospitals, Ann Arbor, Michigan
- St. Joseph Mercy Hospital, Ypsilanti, Michigan
- Henry Ford Hospital, Detroit, Michigan
- St. Mary's Hospital/Butterworth/Blodgett, Grand Rapids, Michigan
- Butterworth Hospital, Grand Rapids, Michigan
- William Beaumont Hospital, Royal Oak, Michigan
- Providence/Sinai Hospitals, West Bloomfield, Michigan
- Michigan State University, East Lansing, Michigan

Louisiana:

- Ochsner Clinic, Ochsner Therapy Center, New Orleans, Louisiana

Pennsylvania:

- Milton S. Hershey Medical Center, Hershey, Pennsylvania

Canada:

- Etobichoke Hospital, University of Toronto, Toronto, Ontario

MBROS Publications:

1. Cederna P, Wilkins EG, Lowery JC, Perkins AJ. Prospective analysis of psychosocial outcomes in post-mastectomy breast reconstruction. *Surgical Forum* 1997; 47:607-609.
2. Lowery JC, Wilkins EG, Kuzon WM. Analysis of instruments for assessment of aesthetic outcomes in breast reconstruction. *Annals of Plastic Surgery* 1996; 36:601-607.
3. Wilkins EG, Lowery JC, Smith DJ. Outcomes research: a primer for plastic surgeons. *Annals of Plastic Surgery* 1996; 37:1-11.
4. Wilkins EG, Lowery JC, Kuzon WM, Perkins A. Functional outcomes in postmastectomy breast reconstruction: preliminary results of the Michigan Breast

Reconstruction Outcome Study. Surgical Forum 1997; 48:
609-612.

For more information about the Michigan Breast
Reconstruction Outcome Study, contact:

Dr. Edwin Wilkins
2130 Taubman Center
1500 East Medical Center Drive
Ann Arbor, MI 48109-3040
ewilkins@umich.edu

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Web Site

Web Site Concept, Design, and Construction: Elizabeth Steinberger RN, MA, MPH

Web Site Maintenance: Sherry Goldfarb MPH, Steve Haskin MA

Text

Implants: Kris Paliwoda MPH

Natural Tissue Reconstruction: Aartee Phatak MPH

Prostheses, Breast Lift, Your Plastic Surgeon, Insurance Issues: Sara Skinner MPH

All Other Text: Elizabeth Steinberger RN, MA, MPH

Breast Reconstruction Vignettes: All personal breast reconstruction stories have been graciously provided by participants in the Michigan Breast Reconstruction Outcome Study. All identifying information has been withheld to preserve anonymity.

Editing, Resource List: Kris Paliwoda MPH, Aartee Phatak MPH, Sara Skinner MPH, Elizabeth Steinberger RN, MA, MPH

Scientific Editor: Edwin Wilkins MD, MPH

Illustrations

MBROS Consumer's Guide to Breast Reconstruction Logo: Elizabeth Steinberger RN, MA, MPH

Medical Illustrations: Tanya Leonello MSA, [Biomedical Communications](#)

Reconstruction Photos: Yvette Salamay, Michigan Breast

Reconstruction Outcome Study

Implant/Tissue Expander Photos: Courtesy of McGhan Medical Corporation

Risk Illustrations: Elizabeth Steinberger RN, MA, MPH

Paintings:

Courtesy of the Web Museum, Paris, France (U.S. mirror site: <http://metalab.unc.edu/wm>).

- Home: "Alphonsine Fourmaise" by Pierre-Auguste Renoir, 1879
- Site Map: "Le Bar aux Folies Bergere" by Edouard Manet, 1881-1882
- Your Decision: "Nave Moe" by Paul Gauguin, 1894
- MBROS Study Results--Reconstruction: "Portrait of Gabrielle Borreau" by Gustave Courbet, 1862
- No Reconstruction: Detail from "AreaArea" by Paul Gauguin, 1892
- No Replacement: "Andromeda" by Eugene Delacroix, 1852
- Prostheses: Detail from "AreaArea" by Paul Gauguin, 1892
- Reconstruction Index: Detail from "Turkish Bath" by Jean-Auguste-Dominique Ingres, 1862
- Implant Index: "Bathsheba at Her Bath" by Rembrandt, 1654
- Implant Surgery: "Study for Nude in Sunlight" by Pierre-Auguste Renoir, 1875-1876
- Saline vs. Silicone: Detail from "The Sabine Women Enforcing Peace by Running Between the Combatants" by Jacques-Louis Davis, 1794-1799
- Implant Advantages: "Gabrielle With a Rose"; by Pierre-Auguste Renoir, 1911
- Implant Disadvantages: Detail from "Joseph Accused by Potiphar's Wife" by Rembrandt, 1655
- Implant Risks: Detail from "The Bathers" by Jean-Honore Fragonard, 1765.
- Natural Tissue Reconstruction Introduction: Detail from "Les Baigneuses" by Pierre-Auguste Renoir, 1918
- TRAM Surgery: Detail from "Bathers" by Pierre-Auguste Renoir, 1918-1919

- TRAM Advantages: Detail from "The Union of Earth and Water" by Peter Paul Rubens, 1618
- TRAM Disadvantages: "Diana Leaving Her Bath" by Francois Boucher, 1742
- TRAM Risks: "Hendrickie Bathing in a River" by Rembrandt, 1654
- Latissimus Dorsi Surgery: "The Source" by Gustave Courbet, 1868
- Other Donor Sites: Detail from "Turkish Bath" by Jean-Auguste-Dominique Ingres, 1862
- MBROS Study Results--Implants vs. Natural Tissue Reconstruction: "The Psyche" by Berthe Morisot, 1876

- Reconstruction Issues: "The Laundress" by Pierre-Auguste Renoir, 1880
- Timing of Surgery: "Study: At the Water's Edge" by Berthe Morisot, 1864
- MBROS Study Results--Timing of Surgery: "The Source" by Jean-Auguste-Dominique Ingres, 1856
- Your Plastic Surgeon: "Odalisque With a Slave" by Jean-Auguste-Dominique Ingres, 1840
- Insurance Issues: "Woman Weighing Pearls" by Jan Vermeer, 1662-1664
- Mammography After Reconstruction: Detail from "Allegory on the Blessings of Peace" by Peter Paul Rubens, 1629-1630
- MBROS Study Results--Mammography of TRAMs: Detail from "Turkish Bath" by Jean-Auguste-Dominique Ingres, 1862

- Breast Replacement Options Summary: Detail from "Bathers" by Pierre-Auguste Renoir, 1918-1919

- Surgical Options After Reconstruction: "Madame d'Haussonville" by Jean-Auguste-Dominique Ingres, n.d.
- Nipple Reconstruction: "Apres le Bain" by Pierre-Auguste Renoir, 1910
- Breast Lift: Detail from "Large Bathers" by Paul Cezanne, 1899-1906
- Breast Reduction: "Young Girl Seated" by Paul-Auguste Renoir, 1909
- Breast Augmentation: "Venus Standing in a Landscape" by Lucas Cranach the Elder, 1529
- Additional Surgeries After Reconstruction Options Summary: "Seated Bather" by Pierre-Auguste Renoir, 1883-1884

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- Renoir, 1874-1876
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- About MBROS: Detail from "Femmes de Tahiti [Sur la Plage]" by Paul Gauguin, 1893
- Credits: "The Needlewoman" by Diego Velasquez, 1640

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